

# **EXHIBIT C**

Page 1

1 UNITED STATES DISTRICT COURT  
2 DISTRICT OF NEW JERSEY  
3 CAMDEN VICINAGE  
4 MDL No. 2875

5 -----x  
6 IN RE:

7 VALSARTAN, LOSARTAN and IRBESARTAN  
8 PRODUCTS  
9 LIABILITY LITIGATION

10 -----x

11 August 13, 2021  
12 9:12 a.m.

13 14 15 16 17 VIDEOTAPED DEPOSITION of STEPHEN  
18 LAGANA, MD, held at the offices of  
19 Greenberg Traurig LLP, located at 445  
20 Hamilton Avenue, 9th Floor, White Plains,  
21 New York 10601, before Anthony Giarro, a  
22 Registered Professional Reporter, a  
23 Certified Realtime Reporter and a Notary  
24 Public of the State of New York.

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1 THE VIDEOGRAPHER: Good 2 morning, everyone. We are going on 3 the record at 9:12 a.m., Eastern Time 4 on Friday, August 13th, 2021. Please 5 note that the microphones are 6 sensitive and may pick up whispering, 7 private conversations and cellular 8 interference. 9 This is Media Unit 1 of the 10 video-recorded deposition of 11 Dr. Stephen Lagana, in the matter of 12 In Re: Valsartan, Losartan, et al. 13 This was filed in the United States 14 District Court for the District of 15 New Jersey, Camden, Vicinage. The 16 docket number is 2875. This 17 deposition is being held via video 18 conference. 19 My name is Corey Wainaina 20 from the firm Veritext Legal 21 Solutions. And I am the 22 videographer. The court reporter is 23 Anthony Giarro from the firm Veritext 24 Legal Solutions. 25 I am not authorized to	Page 7	Page 9

<p>1        Would you like to read and 2 sign the deposition so I don't forget to 3 ask that question? 4        MR. SLATER: We'll talk 5 about that later. 6        Q      I think you've been deposed 7 at least a couple of times before; is 8 that correct? 9        A      I have. 10      Q     And I know -- tell me how 11 many times you've been deposed. 12      A     Two that I recall. 13      Q     One of them was in the 14 Benicar litigation with Mr. Slater; is 15 that right? 16      A     Yes. 17      Q     What was the other one? 18      A     It was a medical 19 malpractice. 20      Q     Was that the same one you 21 testified at trial, the Matthews versus 22 Leslie case? 23      A     No. 24      Q     What was the other 25 deposition you gave?</p>	Page 10	<p>1 doesn't make sense, please let me know. 2 If I talk too fast, which sometimes 3 happens, let me know also; is that okay? 4        A      Thank you. 5        Q     And I think we'll have a 6 good communication today. But again, if 7 there's anything that you need or I don't 8 make myself clear about, please ask me; 9 okay? 10      A     Thank you. 11      Q     And if you answer my 12 questions, I'll assume you understood 13 them. 14      A     Okay. 15      Q     I know you brought with you 16 a number of items today. Also, counsel 17 who retained you sent us a bunch of 18 things. And we'll get through some of 19 those logistics as we go. 20      But I take it you have with 21 you what you think you need to answer 22 questions today? 23      MR. SLATER: Objection. You 24 can answer. 25      Q     I notice you have your</p>
<p>1        A     I don't remember the name of 2 any of the litigants. But the general 3 gist was whether a patient had been 4 released from the hospital too 5 prematurely or not. And I was hired by 6 the defense in that case. 7        Q     Roughly what time frame was 8 that? I know it was earlier than four 9 years ago. But any idea when that was? 10      A     Probably around four years 11 ago. 12      Q     Were you on the side of the 13 hospital or the doctor? 14      MR. SLATER: Object to form. 15      A     Might have been both. I 16 don't entirely recall. But one or the 17 other or both. 18      Q     So I know you've been 19 deposed before. Obviously, if you need 20 to take a break for any reason, let me 21 know. I'm not going to go through a 22 whole long introductory spiel like 23 sometimes you'll get about what my 24 questions are. If you need a break, let 25 me know. If I ask a question that</p>	Page 11	<p>1 report there in laminated fashion, and 2 you have that by your side; right? 3        A     I do. 4        Q     So as a little bit of 5 background, my understanding in terms of 6 your prior legal experience is that 7 you've testified two times at trial, once 8 in 2019, and that was a recent one, 9 Matthews versus Leslie case in the Bronx 10 Supreme Court? 11      A     Yeah. 12      Q     And that was a medical 13 malpractice case, testifying about your 14 field of specialty, that is anatomic 15 pathology; correct? 16      MR. SLATER: Objection. You 17 can answer. 18      A     Well, I am an anatomic 19 pathologist. And I've testified as both 20 a pathologist and as a medical provider. 21      Q     You agree that your field of 22 specialty is anatomic pathology; correct? 23      MR. SLATER: Objection. You 24 can answer. 25      A     Yes. I'm a medical doctor</p>

1 with postgraduate training in anatomic 2 pathology. 3 Q What you hold yourself out 4 as, as an anatomic pathologist, when we 5 look at your Web site or when we read 6 your depositions, that sort of thing; 7 correct? 8 MR. SLATER: Objection to 9 form. 10 A Again, as a physician, I 11 have a medical degree. So I have 12 knowledge of medicine beyond just 13 anatomic pathology; in fact, an anatomic 14 pathologist needs to have grounding in 15 general. But I am a practicing anatomic 16 pathologist. 17 Q And let's just agree that 18 you're a medical doctor or you wouldn't 19 have an M.D.; correct? 20 A That's correct. 21 Q But beyond that in terms of 22 specialization, your specialty is 23 anatomic pathology; correct? 24 A Correct. 25 Q You've testified in another	Page 14	1 Q In the Benicar litigation, 2 Mr. Slater and his law firm hired you; 3 correct? 4 A Correct. 5 Q And in this case, you gave 6 an expert witness report under Rule 26 7 like you did here; correct? 8 A I don't know what Rule 26 9 is. 10 Q You gave an expert report? 11 A I did. 12 Q And you also gave a 13 deposition; correct? 14 A I did. 15 Q And Mr. Slater was there 16 defending you; right? 17 A No, not on trial. 18 Q That's what we say when an 19 attorney defends a deposition. I don't 20 mean a trial. 21 He was there defending your 22 deposition as an expert witness? 23 MR. SLATER: Objection. 24 A He was there as plaintiff's 25 attorney. And I was an expert.	Page 16
1 trial, other than Mathews, another med 2 mal one? 3 A Correct. 4 Q Was that the same one you 5 gave the recent deposition about the 6 patient being released prematurely? 7 A No. 8 Q What was the other medical 9 mal one? 10 A Other medical mal one was -- 11 nothing at all that relates to this. 12 It's something -- I forget if it was a 13 hernia repair that maybe didn't go as 14 planned. There was a bowel injury, along 15 those lines. 16 Q That was the Matthews versus 17 Leslie case in 2019. 18 Is it possible that you 19 covered the same areas? 20 A Yeah. 21 Q You've done 30 to 40 cases 22 where you've reviewed cases as an expert 23 witness? 24 A I believe that's 25 approximately correct.	Page 15	1 MS. COHEN: Let's go off the 2 record. 3 THE VIDEOGRAPHER: We are 4 now off the record. The time is 5 9:23 a.m. 6 (A short recess was taken.) 7 THE VIDEOGRAPHER: We are 8 now back on the record. The time is 9 9:31 a.m. Eastern Time. 10 Q So, Doctor, I'm going to 11 give this another shot. Hopefully, I'll 12 try to keep my voice up. And this will 13 work. When we broke, we were talking 14 about your work in the Benicar 15 litigation. 16 In Benicar, you gave an 17 expert witness report in that case, much 18 like you did here; correct? 19 A Yes. 20 Q And then you also gave a 21 deposition, and at the deposition was 22 Mr. Slater present there; correct? 23 A Correct. 24 Q You talked about your review 25 of cases.	Page 17

1        Does that sort of summarize 2 and recap your expert witness work that 3 you've done? 4    A    Yeah. I would say so. 5    Q    In this case, we'll go 6 ahead, and we'll obviously be going 7 through your report and some of the 8 information that you've read today. 9       Let's just start with 10 stating your full name for the record. 11   A    Sure. Stephen Lagana. 12   Q    And where do you practice? 13   A    I'm on the faculty at 14 Columbia University Medical Center. 15   Q    And you're part of the 16 anatomic pathology division, if you will? 17   A    Yes. 18   Q    And is that part of 19 pathology, one division of pathology? 20   A    Correct. 21       MS. COHEN: In this case, 22 let's go ahead and mark his report. 23 We'll make that Exhibit 1. 24       (The above-referred-to 25 document was marked as Exhibit 1 for	Page 18	1       ask to have that put up there, 2 please. 3       THE VIDEOGRAPHER: Going 4 forward, if you do screen share a 5 document, would you like to see the 6 witness only or the document and the 7 witness? 8       MS. COHEN: Yes. Let me 9 make that clear. When we mark 10 exhibits, I'll announce what the 11 exhibit is. But we don't need to 12 screen share it. People can pull it 13 up if they want to. But I'm not 14 asking for the document to be pulled 15 up; okay? 16       THE VIDEOGRAPHER: Thank 17 you. 18   Q    Just on the date issue, 19 Doctor, we have July 6th as the day that 20 the report was sent to us by Mr. Slater. 21       I take it July 26th is just 22 the wrong date? 23   A    That sounds reasonable. 24       MS. COHEN: We'll mark the 25 July 6th letter as Exhibit 2.	Page 20
1       identification, as of this date.) 2    Q    And we'll have that put up. 3 I think you have that already. 4    A    I do. 5    Q    Now, in your report -- I 6 just want to start looking a little bit 7 here -- on page 1, you understand this is 8 what we call your official expert witness 9 report in this case; correct? 10      MR. SLATER: Objection. 11   A    I do. 12   Q    And although you didn't take 13 an oath like you did at the deposition, 14 you signed it on page 33; correct? 15   A    I did. 16   Q    If you go to page 33, is 17 that date of July 26th incorrect? 18   A    I don't remember. 19   Q    We'll get that straight. I 20 believe that -- 21       THE VIDEOGRAPHER: Counsel, 22 sorry to interrupt. You want to have 23 the document and the witness for the 24 video record? 25       MS. COHEN: No. We did not	Page 19	1       (The above-referred-to 2 document was marked as Exhibit 2 for 3 identification, as of this date.) 4    Q    And I'll show it to you. I 5 take it, it was just a mistype, if you 6 will. 7    A    It might be. 8    Q    I'll show you the letter, 9 Exhibit 2, a July 6th letter where 10 Mr. Slater sent the reports. Tell me if 11 you've seen this before. 12   A    I haven't seen that. Okay. 13 I don't have an argument. It's certainly 14 possible I mistyped the date. There's 15 only one report. 16   Q    Only one report. 17       You understand -- and, 18 again, in this report, you start with a 19 sentence that says, "This report sets 20 forth my opinions with regard to the 21 question of whether ingestion of NDMA and 22 NDEA as a contaminant or impurity of 23 Valsartan (hereinafter 'contaminated 24 Valsartan') can cause cancer in humans." 25       You understood that was the	Page 21

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1 question you were being called on to 2 answer in this phase of the litigation; 3 correct? 4 MR. SLATER: Objection. You 5 can answer. 6 A I knew that that was the 7 purpose of the litigation. 8 Q That was the question that 9 Mr. Slater gave to you when he framed 10 your question to you; correct? 11 MR. SLATER: Objection. You 12 can answer. 13 A That's perhaps a little bit 14 more narrow than everything I've looked 15 at. 16 Q Right. 17 But you start your report by 18 saying the question of whether -- and I 19 won't repeat it again. That was the 20 question that Mr. Slater told you, was 21 the question for you to start with; 22 correct? 23 MR. SLATER: Objection. You 24 can answer. 25 A That was certainly the main	Page 22	1 A No. 2 Q You don't know anything 3 about his credentials; correct? 4 A Correct. 5 Q I turned to the defense 6 experts, and I said there were nine 7 defense experts, and I think you 8 confirmed that you received 9 Dr. Catenacci's, the oncologist, report? 10 A Correct. 11 Q And you said that you read 12 the last part of that report? 13 A Correct. 14 MR. SLATER: Objection. 15 Those are of a much broader 16 conversation. 17 Q When did you receive that 18 report? 19 A About roughly five days ago. 20 Q And in terms of volume you 21 received, just that one, you don't know? 22 A That's right. 23 Q Did you ask for specific 24 ones or were you just given that one? 25 A I didn't ask for specific	Page 24
1 issue. I don't know if that encompasses 2 every aspect. 3 Q And that question was 4 presented to you by Mr. Slater; correct? 5 A Yes. 6 THE VIDEOGRAPHER: We are 7 now off the record. The time is 8 9:38 a.m. Eastern Time. 9 (A short recess was taken.) 10 THE VIDEOGRAPHER: We are 11 back on the record. The time is 12 9:43 a.m. Eastern Time. 13 Q It sounds like in terms of 14 the other plaintiffs' expert witnesses, 15 you did not read their reports; correct? 16 A I did not. 17 Q You're aware the existence 18 of some of the other plaintiffs' experts; 19 correct? 20 A Correct. 21 Q You don't know anything 22 about Dr. Panigrahi, who's also a 23 pathologist; correct? 24 A No. 25 Q Never heard of him; correct?	Page 23	1 ones. I think I asked Adam if there are 2 any that were relevant that were talking 3 about the same papers, given that I had 4 very limited time. There wasn't much 5 time between then and now. If there were 6 any he thought I should read, I would be 7 happy to do so. 8 Q He sent you back the 9 Catenacci, the oncology defense expert 10 report? 11 A Correct. 12 Q Are you aware of who the 13 other eight are? 14 A I am not. 15 Q Were any of them mentioned 16 to you? 17 A No. 18 Q Do you know who, for 19 example, Dr. Chodosh is, a cancer 20 biologist? 21 A No. 22 Q What about Dr. Gibb, an 23 epidemiologist? 24 A No. 25 Q Do you know Dr. Johnson, a	Page 25

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<p>1 toxicologist who came out with a recent 2 article on NDMA and NDEA? 3 A No. 4 Q Never heard of him? 5 A Not that I recall. 6 Q Did you read his article? 7 A We'd have to check the list. 8 Q Sitting here right now, do 9 you have any recollection of reading 10 Dr. Johnson's recent article that came 11 out in 2021? 12 A I might recall the article. 13 I don't recall the name. I'd have to see 14 what article we're talking about. 15 Q And, again, to date, sitting 16 here, you don't have any other expert 17 reports on the defense, other than 18 Dr. Catenacci, to your knowledge? 19 A Correct. 20 Q In terms of the materials in 21 this case, and we'll get into some more 22 of this as we go -- you provided to us -- 23 let me start with this, your expert 24 witness report, which we have marked as 25 Exhibit 1 already. It has attached to it</p>	Page 26	<p>1 can answer. 2 A Well, it's a little bit of a 3 hard question to answer because as far as 4 specific issues related to causation, 5 then these are the materials I relied on. 6 But, of course, I didn't address this 7 question in a vacuum. I addressed it as 8 a doctor who's been to medical school and 9 has practiced for however many years, ten 10 years or so that I've been practicing. 11 So my thinking is shaped by 12 not just the specific articles cited 13 here, but my training and background and 14 experience. But as far as specific 15 reliances for this report, yes, they're 16 all included here with the exception of 17 the one that Chris should have provided 18 to you last night. There was one article 19 I got my citation mixed up. And I 20 thought I was referencing two articles by 21 the same person, published in the same 22 year. So one reference is missing. 23 Q Understood. And I think you 24 have that here. But let me ask it this 25 way.</p>	Page 28
<p>1 a list of the references cited. And it 2 goes from pages 34 to 37. 3 Is it fair to say that at 4 the time you issued your report, which is 5 Exhibit 1, these were the materials you 6 considered? 7 A Yes. 8 Q And either things that are 9 referenced in the expert report or on 10 that list; correct? 11 MR. SLATER: Objection. 12 A Everything on this list is 13 referenced in the report. 14 Q Got it. 15 And we received over the 16 last couple of days some supplemental 17 lists which we'll mark at some point 18 today. And some of that I think is 19 contained in here. 20 But is it fair to say that 21 everything -- again, in terms of issuing 22 your opinions on July 6th, which is the 23 date I think we agree it came out -- that 24 all encompasses Exhibit 1? 25 MR. SLATER: Objection. You</p>	Page 27	<p>1 understand that your 2 background, training and experience and 3 all of that informs your opinions; 4 correct? 5 A Correct. 6 Q That's the point you're 7 making; right? 8 MR. SLATER: Objection. You 9 can answer the question. 10 A Yes. 11 Q But in terms of specific 12 references and materials reviewed, that's 13 what's attached in the references that I 14 just referred to, to your report; 15 correct? 16 MR. SLATER: Objection. You 17 can answer again. 18 Mischaracterization of testimony. 19 Q References cited, pages 34 20 to 37, those are the references you gave 21 in your report; correct? 22 MR. SLATER: Objection. 23 That's a continuation of a prior 24 inappropriate question. I object. 25 You can answer.</p>	Page 29

<p>1 A Yes, with the addition of 2 the paper that we sent over last night. 3 Q The one article that Chris 4 cited? 5 A Yes. 6 Q Let me give you the exact 7 names so I have it here. Let's see. 8 Mr. Geddis said first citation, 36, on 9 page 16 should be Jakuszyn P Gonzalez, CA, 10 the nitrosamines article. 11 A Correct. 12 Q That's the document I'm 13 talking about. 14 A Yes. 15 Q With that substitution, this 16 reference list is what you had at the 17 time to formulate your opinions; correct? 18 A Yes. 19 MS. COHEN: I want to mark 20 his curriculum vitae. It's 21 unfortunately not marked. 22 (The above-referred-to 23 document was marked as Exhibit 3 for 24 identification, as of this date.) 25 Q Let me hand that to you.</p>	<p>Page 30</p> <p>1 when I was preparing for a promotion a 2 couple of years ago, two and a half years 3 ago, I had to make a CV that conformed 4 exactly to the Columbia format. And 5 since then, I've only used this document 6 which conforms with the Columbia format. 7 Q What promotion are you 8 talking about? Are you talking about 9 from assistant professor of pathology to 10 associate professor of pathology? 11 A Precisely. 12 MS. COHEN: I'm going to 13 have the Benicar marked as well and 14 the attached curriculum vitae while 15 we talk about this. And that one is 16 attached there. So we'll mark it as 17 Exhibit 4. 18 A Okay. 19 (The above-referred-to 20 document was marked as Exhibit 4 for 21 identification, as of this date.) 22 Q And what you're saying is, 23 it was in a different format when you 24 were an assistant professor? 25 MR. SLATER: Objection.</p>
<p>1 A Okay. 2 Q Just confirm if that's your 3 curriculum vitae. 4 MR. SLATER: This is now 5 Exhibit 2? 6 MS. COHEN: Exhibit 3. 7 A It appears to be current up 8 until the 5th of April. 9 Q And I have a quick question 10 about this. I know your curriculum vitae 11 from the Benicar litigation obviously was 12 different. It's an earlier time, back in 13 2016. 14 Do you have a different 15 curriculum vitae for different purposes 16 or is this your current curriculum vitae 17 for all purposes? 18 A This is my curriculum vitae 19 for all purposes. 20 Q And so the one that was used 21 in Benicar is just an updated, is what 22 you're saying? 23 A I don't know what the CV for 24 Benicar was. But Columbia University has 25 a very precise format for promotion. And</p>	<p>Page 31</p> <p>1 You're saying what he just said. 2 Q It was a different format of 3 your curriculum vitae? 4 MR. SLATER: I don't 5 understand what the question is. Can 6 you literally just walk me through 7 the CVs? 8 MS. COHEN: Adam -- 9 MR. SLATER: It's a 10 confusing question. 11 MS. COHEN: Adam, you don't 12 have to talk. No speaking 13 objections. It's a very simple 14 question. 15 Q Again, you had a very 16 different curriculum vitae style and 17 approach back in the Benicar litigation. 18 And I think you attribute 19 that to going from assistant to 20 associate; is that correct? 21 MR. SLATER: Objection to 22 the form of the question. You can 23 answer. 24 A Well, before I went for a 25 promotion, I had a CV format that I</p>

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<p>1 probably got from a Microsoft Word 2 template. And then when I decided to go 3 for a promotion or was invited to go for 4 a promotion, I had to put all the data in 5 the Columbia format which is what you 6 have before you.</p> <p>7 Q And that was because you 8 went from assistant to associate?</p> <p>9 A Yes.</p> <p>10 Q And that was in December of 11 2018; is that correct?</p> <p>12 A Sounds correct.</p> <p>13 Q That's because you went from 14 assistant to associate professor. And 15 was that in 2018?</p> <p>16 A Yes.</p> <p>17 Q Is there anything else in 18 terms of the content of the CVs that you 19 think would have been different?</p> <p>20 MR. SLATER: Are you asking 21 him to state and compare them one by 22 one right now? Is that the question?</p> <p>23 MS. COHEN: If you have an 24 objection, say objection. I'm asking 25 my questions.</p>	<p style="text-align: right;">Page 34</p> <p>1 hard to hear. 2 MR. SLATER: I objected to 3 the form of the question. 4 THE COURT REPORTER: I'm 5 very uncomfortable continuing under 6 these circumstances. I'm sorry. 7 MS. COHEN: Maybe we'll just 8 bring him in here or bring him in the 9 hallway or something like that. 10 Let's take a break. We'll take a 11 break and do that. 12 THE VIDEOGRAPHER: We are 13 now off the record. The time is 14 9:57 a.m. Eastern Time. 15 (A short recess was taken.) 16 THE VIDEOGRAPHER: We are 17 back on the record. The time is 18 10:08 a.m. Eastern Time. 19 Q So, Doctor, thank you for 20 being patient on all this. 21 A Sure. 22 Q And I just organized in 23 front of you so we have it all. We 24 have -- 1 is the report; 3 is the CV that 25 went with your report; 4 is the Benicar</p>
<p>1 MR. SLATER: I'm asking you 2 to clarify. Do you want to clarify? 3 I object to the question.</p> <p>4 Q Is there anything else that 5 you know that's different between them?</p> <p>6 A Well, there are specific 7 things that Columbia requires in the 8 Columbia format. And there may be -- no 9 place for other things. And I might have 10 included it in a more informal CV. So I 11 can't be sure that everything 12 substantive -- I mean everything 13 important, should be the same. I don't 14 know if there are minor things that 15 either didn't get transferred or what 16 have you.</p> <p>17 Q Fair enough.</p> <p>18 And other than, again, going 19 from assistant professor of pathology 20 with a specialty in anatomic pathology, 21 from assistant to associate in 2018, what 22 you do every day has been the same; 23 correct?</p> <p>24 MR. SLATER: Objection.</p> <p>25 THE COURT REPORTER: It's</p>	<p style="text-align: right;">Page 35</p> <p>1 report. We're waiting on a copy of 2 2 which is the letter. And then I'm going 3 to mark as Exhibit 5, what was sent to us 4 last night by Mr. Geddis. 5 Just again for completeness 6 sake, is that the article you said you 7 needed to be -- I think you had the wrong 8 cite; is that right?</p> <p>9 A Yeah. Incorrect citation.</p> <p>10 Q So this article now is the 11 right one that goes with your reliance 12 list, if you will, reference list?</p> <p>13 A Yeah. The reference that's 14 in the -- that's in the report now is 15 also the reliance and reference. This 16 one was missing. So this adds to what's 17 here.</p> <p>18 Q I see what you're saying.</p> <p>19 A It only replaces in that one 20 specific sentence.</p> <p>21 Q And two, I'm going to hand 22 you this letter. That is the correct 23 one --</p> <p>24 MR. SLATER: I think we're 25 all going to have to put our masks on</p>

<p>1 if we're not questioning. I hate to 2 do this. It's just too many people 3 in here.</p> <p>4 Q Again, this is Exhibit 2 5 which is the July 6th letter. And I do 6 want to look at the last page of this. 7 And --</p> <p>8 MR. SLATER: Which exhibit 9 is this?</p> <p>10 MS. COHEN: Exhibit 2.</p> <p>11 MR. SLATER: I don't think I 12 have it. I have no e-mail on my 13 computer.</p> <p>14 Q So you have that in front of 15 you. It says that your rate is \$600 per 16 hour, except for depositions and 17 courtroom testimony, which is \$5,000 per 18 hour; is that correct?</p> <p>19 A That's what it says. That 20 is not correct.</p> <p>21 Q That's not correct?</p> <p>22 A No. That would be lovely. 23 But, no, \$6,000 per day for deposition 24 and courtroom testimony.</p> <p>25 Q Do you know why it says</p>	<p>Page 38</p> <p>1 A Could you read it again, 2 please?</p> <p>3 Q Sure.</p> <p>4 The central question of this 5 stage of the litigation is whether 6 exposure to NDMA and/or NDEA at the 7 dosage to which plaintiffs were 8 potentially exposed via ingestion of 9 Valsartan and within the time frame of 10 which they were potentially exposed could 11 have caused the types of cancer in human 12 beings that are claimed in this 13 litigation; in other words, and I'll ask, 14 adding in the doses and the time frames, 15 you agree those are significant features 16 of the question; right?</p> <p>17 MR. SLATER: Objection. You 18 could answer.</p> <p>19 A I don't agree with 20 everything in that statement.</p> <p>21 Q Do you disagree that the 22 doses matter?</p> <p>23 MR. SLATER: Objection to 24 this entire line because it's built 25 on a false premise. You can answer.</p>
<p>1 \$5,000 an hour?</p> <p>2 A I could only presume it's a 3 typographical error.</p> <p>4 Q But it's \$6,000 per day?</p> <p>5 A Yes.</p> <p>6 Q Not \$5,000 per hour?</p> <p>7 A Correct.</p> <p>8 Q We'll put that aside for 9 now. Now, one thing I want to ask you is 10 that -- well, let me ask.</p> <p>11 In Dr. Chodosh's expert 12 report, I know you haven't seen this, he 13 says that the central question at this 14 stage of this litigation is whether 15 exposure to NDMA and/or NDEA at the doses 16 to which plaintiffs were potentially 17 exposed via ingestion of Valsartan and 18 within the time frame of which they were 19 potentially exposed could have caused the 20 types of cancer in human beings that are 21 claimed in this litigation.</p> <p>22 You don't disagree that 23 that's a central question, do you?</p> <p>24 MR. SLATER: Objection for 25 multiple reasons. You can answer.</p>	<p>Page 39</p> <p>1 A Understanding that there is 2 no safe dosage and that any exposure is 3 likely to increase risk of cancer, I 4 would -- from that baseline, I would 5 agree that bigger doses for longer 6 duration are worse than smaller doses for 7 shorter durations. Likely, likely.</p> <p>8 Q You wouldn't have any 9 quarrel with an expert, whether on the 10 defense side or the plaintiffs' side, 11 that includes the issue of doses and the 12 issue of time frame in terms of looking 13 at this issue; correct?</p> <p>14 MR. SLATER: Objection. You 15 could answer.</p> <p>16 A It's an extremely broad 17 proposition. But in general, I think 18 looking at the dose and length of 19 exposure are both reasonable things to 20 consider.</p> <p>21 Q And should be considered 22 when looking at the issue of general 23 causation and cancer; correct?</p> <p>24 MR. SLATER: Objection. You 25 could answer.</p>

1 A Certainly, but with some 2 humility for what we don't know, insofar 3 as there is no safe baseline level of 4 NDMA. 5 Q Your answer is those have to 6 be considered; true? 7 MR. SLATER: Objection. You 8 could answer. 9 A Those are factors amongst 10 many which have to be considered. 11 Q Now, just to make sure I 12 cover this, all of the information that 13 you've obtained in this litigation that 14 we have on the table list and that's 15 referenced, did all of that come through 16 Mr. Slater and his firm? 17 MR. SLATER: Objection. You 18 can answer. 19 Q Putting aside your training 20 and experience, all of the references and 21 information came to you from Mr. Slater 22 and his law firm; correct? 23 A Absolutely not. 24 Q You pulled some of it 25 yourself?	Page 42	1 MR. SLATER: Objection. You 2 could answer. 3 A Can you repeat the question? 4 Q Sure. 5 I said you've looked high 6 and low, you've looked everywhere, you've 7 gathered your references, and there's not 8 a single article that establishes that 9 NDMA and NDEA are known carcinogens in 10 humans; correct? 11 MR. SLATER: Objection. You 12 can answer. 13 A I totally disagree with 14 that. 15 Q You have articles that prove 16 in laboratory animals; correct? 17 MR. SLATER: Objection. You 18 can answer. 19 A I wasn't done answering the 20 question. 21 Q Okay. 22 A There are, as referenced in 23 my report, a number of Peer Reviewed and 24 scientific articles looking at dietary 25 NDMA exposure in humans, some of which	Page 44
1 A Almost everything. 2 Q All the literature, you're 3 talking about in your reference list? 4 MR. SLATER: Objection. You 5 could answer. 6 A I didn't keep a record of 7 what was -- what I found myself and what 8 was provided by Mr. Slater. But roughly 9 speaking, I would say 90-some-odd percent 10 of the studies, I found myself, and maybe 11 a few were sent by Mr. Slater. And, of 12 course, all the corporate documents and 13 deposition and stuff was provided by 14 Mr. Slater. 15 Q All the depositions and 16 corporate documents all came through 17 Mr. Slater and his law firm, is what 18 you're saying? 19 A Yeah. 20 Q You would agree that you 21 have looked high and low and gathered the 22 information, and there is not a single 23 article, Peer Reviewed article that 24 proves that NDMA and NDEA are known 25 carcinogens in humans; correct?	Page 43	1 include tens of thousands of patients 2 that do, in fact, show an association 3 between dietary NDMA exposure in cancer. 4 So that's one line of that. 5 As far as a single article, 6 there's nothing in the medical literature 7 that has definitively established by a 8 single article, by the weight of 9 evidence, the totality of the evidence. 10 So looking at those dietary NDMA 11 articles, my opinion to a reasonable 12 degree of medical certainty is that NDMA 13 ingestion is clearly associated with 14 human carcinogenesis. 15 Q So you rely on the dietary 16 articles in your report for an 17 association; correct? 18 A Amongst others. 19 Q You cannot point us to any 20 single Peer Review article that 21 establishes causation in terms of human 22 carcinogens with NDMA and NDEA; correct? 23 MR. SLATER: Objection. You 24 can answer. 25 A It's a large question. It's	Page 45

12 (Pages 42 - 45)

<p>1 hard to drill down to one -- to one, you      2 know, short answer. To some extent, I      3 could say that my -- my report deals      4 entirely with that question and concludes      5 that does, in fact, cause human cancer.      6         However, to try to answer      7 the question, other than just saying read      8 my report, we know the mechanisms by      9 which NDMA causes cancer. It's stated by      10 WHO and IARC that metabolism in      11 experimental models, meaning animals and      12 humans, is likely to be the same. And      13 IARC concludes that NDMA is a probable      14 human carcinogen.      15         And I agree with IARC's      16 assessment based on both epidemiologic      17 studies as they relate to diet, early      18 indications about contaminated Valsartan      19 itself and knowing the mechanism by which      20 NDMA is a potent mutagenic compound.      21         Q   Do you know the difference      22 between association and causation?      23         A   I do.      24         Q   And are you familiar with      25 that from -- let me strike that.</p>	<p>Page 46</p> <p>1 wildly unethical.      2           So we have to infer      3 causation by applying the criteria -- I      4 chose to use Bradford Hill's criteria,      5 although there are other ways of      6 distinguishing between association and      7 causation. I chose Bradford hill. I      8 looked at the totality of the evidence.      9 And my opinion has landed in the same      10 place with WHO and IARC and FDA.      11         Q   We're going to go through      12 all of the articles and your report. I'm      13 just asking you, can you cite -- I'm not      14 saying you can only look at one article.      15         Can you cite to us any      16 article that establishes a Peer Review      17 process, causation as a human carcinogen      18 for NDMA and NDEA?      19         MR. SLATER: Objection. You      20 can answer.      21         Q   You would have it in your      22 report if you could find it; right?      23         MR. SLATER: Objection. You      24 can answer.      25         Q   True?</p>
<p>1           I want to go back to my      2 question which is, you could not point us      3 to any single Peer Review article that      4 establishes causation in terms of human      5 carcinogens with NDMA and NDEA. And you      6 point to, again, the dietary studies,      7 your report, which we'll go through in      8 great depth.      9           Can you point to any single      10 Peer Review article that causes      11 causation?      12         MR. SLATER: Objection. You      13 could answer the question.      14         A   As far as a single article,      15 I think it's an unrealistic -- it's not      16 the way that medical research is      17 evaluated. You don't just look for one      18 article that definitively proves      19 causation. The way to do that would be      20 to do a double blind randomized placebo      21 controlled trial, wherein one group of      22 people who is exactly the same as another      23 group of people get fed massive doses of      24 NDMA. And then you see how many cancers      25 they get. And such a thing would be</p>	<p>Page 47</p> <p>1           MR. SLATER: Objection. You      2 can answer.      3         A   I'm sorry. I think that's      4 three things. I'm asking still about the      5 first. What is the question?      6         Q   Can you cite to us any      7 article, Peer Review literature that      8 establishes NDMA, NDEA as a human      9 carcinogen?      10         MR. SLATER: Objection. You      11 can answer.      12         A   Well, consensus statements      13 by IARC, WHO, FDA, EMA.      14         Q   So the answer's no, no      15 article that you can cite to?      16         MR. SLATER: Objection.      17         A   I think I just said, or      18 publications.      19         Q   I'm asking about Peer Review      20 literature.      21         A   Those are Peer Review.      22 Well, IARC, WHO are Peer Review.      23         Q   We'll circle back to that.      24         You're here as a scientist;      25 correct?</p>

1           MR. SLATER: Objection. You 2 can answer. 3       A I'm here as a physician, 4 medical scientist, yes. 5       Q You're not here as an 6 advocate; correct? 7       A No. 8       Q And you're not leaning 9 towards one side or the other as you look 10 at this case? 11      A Well, I've drawn 12 conclusions. I mean I have an opinion. 13      Q Before you got started, had 14 you ever looked at the issue of NDMA and 15 NDEA as a contaminant or impurity of 16 Valsartan and carcinogen? Have you ever 17 looked at that issue in any capacity 18 outside of this case? 19      A I think, yeah. I must have 20 seen it. It was in the news. I'm sure I 21 looked at it to some extent. 22      Q You first got involved in 23 this case by the invoices, I think in 24 late 2020; correct? 25      A If that's what the invoices	Page 50	1       Q You had never studied that 2 in any capacity prior to your meeting 3 with Mr. Slater; correct? 4       A Whether NDMA causes cancer? 5       Q Yes. 6       A I probably had looked at it 7 before. 8       Q Can you tell me where? 9            MR. SLATER: I'm going to 10 direct you only to answer to the 11 extent that you are not bound by any 12 confidentiality outside of this case. 13      Q Let me ask it this way. I'm 14 not asking about anything that's 15 confidential. 16           In your role as a clinician, 17 an M.D., did you ever look at this issue 18 before you sat down with Mr. Slater? 19           MR. SLATER: Objection to 20 the term "this issue." You can 21 answer. 22           MS. COHEN: This issue of 23 NDMA and NDEA and relationship with 24 cancer. 25       Q Did you ever in any capacity	Page 52
1 say, that sounds correct. 2       Q You started off with an 3 hour-long meeting with Mr. Slater; 4 correct? 5       A Sounds correct. 6       Q He gave you the question 7 that is from the plaintiffs' perspective, 8 whether ingestion of NDMA and NDEA as a 9 contaminant or impurity of Valsartan can 10 cause cancer in humans; correct? 11      A I don't remember the details 12 of what we spoke about. I mean I'm sure 13 we spoke about the case in general. 14      Q He gave you your assignment; 15 correct? 16           MR. SLATER: Objection. 17      A He asked me to look at the 18 issue. 19      Q At that issue; right? That 20 question; correct? 21           MR. SLATER: Objection. You 22 can answer. 23      A He asked me to look at the 24 issue of whether NDMA ingestion can cause 25 cancer in humans.	Page 51	1 in your real world life outside of expert 2 witness work look at this issue? 3       A You know, there have been 4 times when this has come up in the late 5 press. And so I have, you know, looked 6 to some extent at this issue. But as 7 part of my practice of medicine, no. 8       Q As a scientist or clinician 9 or M.D., you had never looked at this 10 issue; correct? 11           MR. SLATER: Objection. You 12 can answer. 13      A Not that I recall. 14      Q And so all of your 15 knowledge, education, experience is 16 derived in litigation in terms of the 17 seminal question at issue in this case; 18 true? 19           MR. SLATER: Objection. You 20 can answer. 21      A To a large extent, this 22 question is about carcinogenesis and 23 carcinogenicity. And I am an anatomic 24 pathologist with a lot of experience 25 diagnosing cancers, staging cancer. So I	Page 53

<p>1 am an expert on cancer.      2 So that, I think, is      3 probably why Mr. Slater contacted me.      4 But as for the sort of ways in which      5 cancer's developed, I know very well, I      6 understand very well the role of NDMA.      7 Precisely in cancer causation, I learned      8 largely by doing research for this      9 litigation.</p> <p>10 Q We'll unpack that statement.      11 I'm going to ask a straightforward      12 question, though.</p> <p>13 In terms of this question,      14 whether ingestion of NDMA and NDEA as a      15 contaminant or impurity of Valsartan can      16 cause cancer in humans, that question,      17 all of your knowledge, research came in      18 litigation; correct?</p> <p>19 MR. SLATER: Objection. You      20 can answer.</p> <p>21 A Well, before this started, I      22 certainly knew that NDMA was a potent      23 laboratory carcinogen for animals. As      24 far as how carcinogenic it was or was not      25 for humans, I don't recall having looked</p>	<p>Page 54</p> <p>1 about this. But there's probably      2 people that would assert objections      3 to him answering those questions.      4 And I'm not involved with that.      5 MS. COHEN: Let's talk on a      6 break.</p> <p>7 MR. SLATER: So I'm not -- I      8 don't think he should answer that      9 question.</p> <p>10 Q Well, let me ask the      11 question.</p> <p>12 Have you consulted with the      13 defense at any point in time on NDMA and      14 NDEA?</p> <p>15 MR. SLATER: Isn't that the      16 flip side to the same question?</p> <p>17 MS. COHEN: I'm phrasing the      18 question. If he doesn't answer,      19 we'll have it on the record.</p> <p>20 MR. SLATER: Why don't you      21 come back to this. And I'll talk to      22 you. I'm telling you it's a question      23 that he can't answer. It's the flip      24 side of the other question. I'm      25 happy to talk to you about it during</p>
<p>1 at that literature in detail before the      2 litigation.</p> <p>3 Q And it's not an issue that's      4 come up in your clinical practice; true?</p> <p>5 A True.</p> <p>6 Q And, in fact, let's go      7 into -- we've talked a little bit about      8 your expert witness work, your legal      9 work. Let me ask you one more question      10 before I move on.</p> <p>11 Have you ever consulted      12 with -- on the issue of NDMA and NDEA      13 with anyone other than Mr. Slater?</p> <p>14 MR. SLATER: You can answer      15 the question with a yes or no. But      16 if you consulted in the capacity that      17 was not disclosed with anybody else,      18 then you won't be allowed to give any      19 of those details. But you can say      20 yes or no to that first question.</p> <p>21 THE WITNESS: Okay.</p> <p>22 A Yes.</p> <p>23 Q Other plaintiffs' attorneys?</p> <p>24 MR. SLATER: Don't answer      25 the question. I'm happy to talk</p>	<p>Page 55</p> <p>1 a break.</p> <p>2 MS. COHEN: Okay.</p> <p>3 Q And you made a comment a      4 minute ago about this is why      5 Mr. Slater -- why you thought Mr. Slater      6 called you.</p> <p>7 The reason he called you is      8 because you and he had worked together      9 before; correct?</p> <p>10 MR. SLATER: Objection. You      11 can answer.</p> <p>12 A I would expect and hope that      13 the reason he called me is because he      14 knows that I am an expert on cancer      15 development and that I would give a      16 thorough and fair evaluation of the      17 literature.</p> <p>18 Q We know you worked for      19 Mr. Slater and his firm on Benicar, that      20 you did a report in 2016, and that you      21 did a deposition in 2017; correct?</p> <p>22 A Yes.</p> <p>23 Q And you and he had worked on      24 some cases before that too; is that      25 right?</p>

<p>1 A No. 2 Q Had you worked on another 3 case with him at any point in time? 4 A Not that I recall. 5 Q Just Benicar, is what you're 6 saying? 7 A Yes. 8 Q I think in the deposition, 9 there was reference to another case. But 10 I think that was part of Benicar cases, 11 perhaps. 12 MR. SLATER: Objection. Do 13 you want to tell us what you're 14 specifically referring to? 15 Q Did you do work with 16 Mr. Slater on anything that was not 17 Benicar-related at any point in time? 18 A No. We worked on -- there 19 were several Benicar cases. 20 Q And you're saying other 21 than -- after Benicar, this is the next 22 involvement you had with Mr. Slater and 23 his law firm? 24 A Yes. 25 Q This being Valsartan?</p>	<p>Page 58</p> <p>1 A I'm a surgical pathologist 2 or an anatomic pathologist. 3 Q Well, there's a difference 4 between them, aren't there? 5 A Between anatomic pathology 6 and surgical pathology? 7 Q Yes. 8 A Surgical pathology is a 9 subcategory of anatomic pathology. 10 Q Let's move a couple of pages 11 in -- one, two, three pages in on that, 12 Exhibit 5. This also says -- again, more 13 description about what you do and who you 14 are -- "I am a surgical pathologist with 15 sub-specialty expertise in GI and liver 16 pathology"; correct? 17 A Correct. 18 Q And that's accurate; right? 19 A It is. 20 Q And what that means is that 21 you primarily study 22 tissues --correct?-- and samples and 23 specimens removed from patients; correct? 24 MR. SLATER: Objection. You 25 can answer.</p>
<p>1 A Correct. 2 Q And the question of NDMA and 3 NDEA; correct? 4 A Yes. 5 Q When we look at your Web 6 site, the Columbia Web site, you're 7 listed as -- I want to move to your 8 medical-clinical practice as opposed to 9 your legal work for just a moment. 10 (The above-referred-to 11 document was marked as Exhibit 5 for 12 identification, as of this date.) 13 Q I'll give you Exhibit 5. 14 Do you recognize this as 15 part of your Columbia Web site? 16 A Yes. Looks correct. 17 Q And what is listed as your 18 specialties: Pathology-anatomic, 19 gastrointestinal pathology; correct? 20 A Yes. 21 Q And that's consistent with 22 how you hold yourself out in terms of 23 your specialty; correct? 24 MR. SLATER: Objection. You 25 can answer.</p>	<p>Page 59</p> <p>1 A Yeah. We look at everything 2 from -- well, we look at everything from 3 clinical history of a patient to the 4 gross organ that's removed. That has to 5 be removed from the patient in surgery. 6 We look for important parts -- if it's a 7 cancer case, we look at a tumor, we make 8 slices of that, turn that into slides, 9 which we stain, and look at glass slides 10 under a microscope, make diagnoses, stage 11 cancers. 12 Q But in terms of how you 13 spend your time as a clinician, first of 14 all, I guess, you said in your report or 15 your deposition that 75 percent of your 16 time is on clinical commitment and 17 reviews of specimen; correct? 18 A Yes. 19 Q And that means again as an 20 anatomic or surgical pathologist; 21 correct? 22 A Correct. 23 Q You're not a 24 cytopathologist; correct? 25 A Correct.</p>

1 Q You're not a forensic 2 pathologist; correct? 3 A I do perform autopsies, but 4 medical autopsies which are different 5 than forensic autopsies. 6 Q I think I read in your 2019 7 deposition that you hadn't done any full 8 autopsies for two years at that point 9 which would have been 2017. 10 Has that changed at all? 11 A Yes. I did autopsies during 12 COVID. 13 Q And is that because of need? 14 A Yes. 15 Q But you don't hold yourself 16 out as a forensic pathologist; correct? 17 MR. SLATER: Objection. You 18 can answer. 19 A Not a forensic pathologist 20 in the sense of going to crime scenes and 21 investigating, no. Medical autopsies, I 22 am fully capable of performing. 23 Q For a while, you hadn't been 24 doing them? 25 A Right.	Page 62	1 can answer. 2 A I'm a codirector of a 3 committee that actually comes up with 4 molecular testing protocols. So I 5 interface between the surgical pathology 6 division and the molecular pathology 7 division to come up with optimal testing 8 protocols. 9 So if someone has a colon 10 cancer diagnosed at Columbia, they get a 11 number of ancillary tests, both within 12 the molecular lab and with anatomic 13 pathology. And I'm the codirector of the 14 committee that decides what those best 15 tests are. 16 Q If we look at your 17 curriculum vitae, either Version 1 from 18 Benicar, Version 2 from Valsartan, we 19 don't see anything calling yourself a 20 molecular pathologist; correct? 21 A I mean the administrative 22 role I just described is on it. But, no, 23 a molecular pathologist is someone who 24 can run the machines. I can't run the 25 machines. But I am going to say -- and	Page 64
1 Q How many years was that? 2 A I did them for a few years. 3 I stopped doing them for a few years. I 4 went back to them last year. I stopped 5 again now. So I didn't keep careful 6 track of it. 7 Q And you're not a molecular 8 pathologist; you don't specialize in DNA 9 and RNA sequencing; correct? 10 MR. SLATER: Objection. You 11 can answer. 12 A Molecular pathology has 13 become really a very integral part of 14 being an anatomic and surgical 15 pathologist. So I do have a very good 16 working knowledge of molecular pathology. 17 And I'm not versed in it in any way. 18 Mainly, though, in interpreting results, 19 I could not run the machine per se to do 20 it. 21 Q You don't hold yourself 22 out -- that's not one of the things you 23 put on your CV or on your Web site that 24 you're a molecular pathologist; correct? 25 MR. SLATER: Objection. You	Page 63	1 I'll defend this -- that I can certainly 2 interpret molecular results very well. 3 Q I went through all the Web 4 sites that I could find online that 5 describe you. And they all list you as 6 an anatomic pathologist. 7 You don't disagree with 8 that, do you? 9 MR. SLATER: Objection. You 10 can answer. 11 A No. I'm an anatomic 12 pathologist. 13 Q That's how you hold yourself 14 out to the world; correct? 15 A Yes. 16 Q Anatomic pathology again 17 primarily consists of tissue evaluation 18 from individual cells, finding the 19 lacerations, evaluations of specimens and 20 tissues; correct? 21 MR. SLATER: Objection. You 22 could answer again. We just went 23 through this for ten minutes. 24 A So anatomic pathology is the 25 study of disease in organs and cells.	Page 65

17 (Pages 62 - 65)

<p>1 And so that is what I do. I look at 2 gross organs. I may look at a whole body 3 in the case of an autopsy. I may look at 4 cells. I may do ancillary tests to look 5 at subcellular structures. Any of that 6 would be part and parcel of my daily 7 practice.</p> <p>8 Q And, again, 75 percent of 9 your time is on this anatomic pathology 10 clinical commitment and review of 11 specimen, I think is how it was 12 described. Does that sound right?</p> <p>13 MR. SLATER: Objection. You 14 can answer.</p> <p>15 A Yeah. Actually, a lot of 16 that also entails teaching. If I have a 17 resident or a fellow assigned to me while 18 I'm doing that work, I'm also teaching.</p> <p>19 Q I'll tell you in a recent 20 trial transcript, Mathews versus Puente 21 case in the Bronx, that was in 2019, 22 nothing has changed about your practice 23 since 2019; correct?</p> <p>24 MR. SLATER: Objection. You 25 could answer.</p>	<p>Page 66</p> <p>1 A Expert for the defense, 2 correct.</p> <p>3 Q And what you said is, "I'm 4 an anatomic -- on line 5, page 5 -- 5 pathologist. What that means, I think 6 perhaps you have heard something about 7 that work before, so I won't go into too 8 much depth. But different than an MD who 9 deal entirely with autopsies, a hospital 10 based anatomic pathologist looks at 11 basically any tissue that can be removed 12 from a person and analyzes it under a 13 microscope"; correct? You said that?</p> <p>14 A I think that's probably a 15 typo. I probably said "different than an 16 ME," medical examiner.</p> <p>17 Q It goes on and says, "If 18 you've ever had a biopsy or a surgery, 19 anything like that, that goes to an 20 anatomic pathology lab and someone like 21 myself will look at it under a microscope 22 and make a diagnosis as to whether 23 something is benign, malignant, inflamed, 24 normal."</p> <p>25 A Okay.</p>
<p>1 A It's generally the same, 2 yeah.</p> <p>3 Q And what you said there -- 4 and I could show you if you want me to 5 get out the transcript --</p> <p>6 MR. SLATER: Let's do that.</p> <p>7 MS. COHEN: That's fine.</p> <p>8 We'll give you a copy of this. We'll 9 mark that as Exhibit 6.</p> <p>10 (The above-referred-to 11 document was marked as Exhibit 6 for 12 identification, as of this date.)</p> <p>13 MR. SLATER: What page of 14 Exhibit 6?</p> <p>15 Q Do you recall giving this 16 testimony in the Bronx court?</p> <p>17 A I do.</p> <p>18 Q And you recall turning to 19 the jury giving this testimony about what 20 you did, what you do?</p> <p>21 A What page are we looking at?</p> <p>22 Q Page 5.</p> <p>23 This is where you're in the 24 medical malpractice case as an expert for 25 the defense, I believe; correct?</p>	<p>Page 67</p> <p>1 Q And then you also describe 2 how -- well, it goes on to -- that's your 3 description to the jury in 2019 in the 4 Bronx about what you do as an anatomic 5 pathologist; correct?</p> <p>6 MR. SLATER: Objection. You 7 can answer.</p> <p>8 A That's what I said at the 9 time. My understanding is that the 10 practice of pathology had been discussed 11 with the jury before. I believe I was 12 under that impression. So I gave sort of 13 a general and high-level view of what an 14 anatomic pathologist does. I could talk 15 for an hour about the details, if we want 16 to. But this is what I said.</p> <p>17 Q You're under oath; correct?</p> <p>18 A Yes.</p> <p>19 Q You swore to tell the truth; 20 correct?</p> <p>21 A Yes.</p> <p>22 Q And you did tell the truth; 23 correct?</p> <p>24 A Oh, yes, that's true.</p> <p>25 Q You're a board-certified</p>

<p>1 anatomic pathologist; correct?</p> <p>2 A I am.</p> <p>3 Q Also, in terms of patients</p> <p>4 as I understand it from looking at prior</p> <p>5 testimony of yours, you sort of team up</p> <p>6 with the doctor who follows the patient</p> <p>7 and sees the patient; in fact, as a</p> <p>8 gastroenterologist in the Benicar</p> <p>9 litigation, for example.</p> <p>10 So there's another doctor</p> <p>11 that teams up with you who provides the</p> <p>12 clinical part; correct?</p> <p>13 MR. SLATER: Objection.</p> <p>14 Mischaracterization. You can answer.</p> <p>15 A Well, the way it works is, a</p> <p>16 pathologist doesn't ever procure or</p> <p>17 almost never -- I never procure my own</p> <p>18 specimen. So anytime that I'm looking at</p> <p>19 a biopsy or a surgical resection, it's</p> <p>20 either a surgeon or gastroenterologist,</p> <p>21 some other physician has collected that</p> <p>22 sample. And that other physician is the</p> <p>23 one who has been seeing the patient,</p> <p>24 talking with the patient and working on</p> <p>25 them.</p>	<p>Page 70</p> <p>1 describe what you see under the</p> <p>2 microscope as you said; correct?</p> <p>3 A That's the main way I</p> <p>4 communicate my results.</p> <p>5 Q 75 percent of your practices</p> <p>6 are on that; correct?</p> <p>7 MR. SLATER: Objection. You</p> <p>8 can answer.</p> <p>9 A Or more. Certainly, there</p> <p>10 are times when a discussion is needed.</p> <p>11 And that could be an e-mail to a</p> <p>12 clinician or a phone call.</p> <p>13 Q 25 percent of your work I</p> <p>14 guess is split between teaching, research</p> <p>15 and administrative tasks, maybe a little</p> <p>16 bit of legal work?</p> <p>17 A Well, the legal work, I try</p> <p>18 to keep on nights and weekends. So my</p> <p>19 official time is for the most part</p> <p>20 clinical work, first and foremost;</p> <p>21 administrative work, which has increased</p> <p>22 over the years, and is continuing to</p> <p>23 increase; teaching and research.</p> <p>24 Q In the clinical pocket,</p> <p>25 again, you're part of a care team;</p>
<p>1 So by the time I get the</p> <p>2 sample, there's a care team. And I'm</p> <p>3 part of the care team, similar to the way</p> <p>4 a radiologist, you know, doesn't go out</p> <p>5 on to the street to pull them into the</p> <p>6 MRI machines. Another doctor refers</p> <p>7 them. So any patient that I see has, you</p> <p>8 know, seen a different physician and is</p> <p>9 working with another physician.</p> <p>10 Q I think that's a correct way</p> <p>11 of looking at it. Part of the team, your</p> <p>12 role again as the anatomic or surgical</p> <p>13 pathologist is to look at the tissues,</p> <p>14 the specimens, you know, that kind of</p> <p>15 thing; correct?</p> <p>16 A In the context of the</p> <p>17 patient, it would be inappropriate to</p> <p>18 just look it in a vacuum. In most</p> <p>19 instances, it's important to know the</p> <p>20 clinical history of the patient,</p> <p>21 presenting the symptoms and to synthesize</p> <p>22 both patient's clinical background and</p> <p>23 what I might see under a microscope.</p> <p>24 Q And, Dr. Lagana, what you do</p> <p>25 is you prepare reports that again</p>	<p>Page 71</p> <p>1 correct?</p> <p>2 A Yes.</p> <p>3 Q You're official role is to</p> <p>4 do the pathology report; correct?</p> <p>5 MR. SLATER: Objection. You</p> <p>6 can answer.</p> <p>7 A Yeah.</p> <p>8 Q When you see patients, it's</p> <p>9 like one and done with your patients;</p> <p>10 correct?</p> <p>11 MR. SLATER: Objection. You</p> <p>12 can answer.</p> <p>13 A Well, that I definitely</p> <p>14 would not say is entirely correct, no.</p> <p>15 Q Largely correct?</p> <p>16 MR. SLATER: Objection. You</p> <p>17 can answer.</p> <p>18 A What do you mean by one and</p> <p>19 done?</p> <p>20 Q Well, how often do you</p> <p>21 follow patients from Point A to Point B</p> <p>22 to Point C? Aren't you doing your</p> <p>23 pathology role where you get specimens</p> <p>24 and not seeing patients?</p> <p>25 MR. SLATER: Objection. You</p>

1 could answer.  
 2 A So really depends on the  
 3 patient. There are some patients, I've  
 4 seen their biopsies for years and years;  
 5 for example, we have an active  
 6 transplantation service at Columbia. So  
 7 there are liver transplant patients who  
 8 I've probably seen 20 biopsies from over  
 9 the years, you know. So I do know -- I  
 10 know their history very well. I know  
 11 what they've had both clinically and  
 12 pathologically.  
 13 Q It's just coincidental --  
 14 MR. SLATER: I'm sorry. He  
 15 was not done talking. I don't think  
 16 you realize it. But please don't  
 17 interrupt him.  
 18 Q Were you finished?  
 19 A I wasn't finished.  
 20 So the patients who require  
 21 frequent biopsies and especially the ones  
 22 who have GI or liver problems, I am quite  
 23 familiar with and do provide some  
 24 continuity of care in that regard.  
 25 Furthermore, there are a lot

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1 A That's the majority. I  
 2 wouldn't say vast majority.  
 3 Q And you team up with a  
 4 clinician who treats the patient, follows  
 5 the patient, discusses things with the  
 6 patient; correct?  
 7 MR. SLATER: Objection to  
 8 the form. And I'm going to just  
 9 state for the record, this is one of  
 10 the multiple areas where counsel has  
 11 continued to ask the same questions  
 12 in the same areas over and over again  
 13 which is not appropriate. It's  
 14 contrary to the protocol in the  
 15 rulings in this case and is going to  
 16 have a significant impact on our  
 17 decision as to whether to file a  
 18 motion for a protective order at the  
 19 conclusion of seven hours on the  
 20 record by defense counsel.

21 MS. COHEN: We're also going  
 22 to keep track of how many speaking  
 23 objections are made. And we're going  
 24 to count those against the time as  
 25 well. I'm entitled to ask my

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1 of times where I'll look at a biopsy or a  
 2 resection, and I'll feel the need to  
 3 check a prior specimen. If we had a  
 4 prior biopsy, you know, I'll want to know  
 5 what was in that one. So I'll go back,  
 6 and I'll look at that.  
 7 So it's not always a  
 8 one-and-done type of thing; you know,  
 9 there are certain times where it is one  
 10 and done if someone has reflux, a  
 11 gastroenterologist does an esophageal  
 12 biopsy that shows reflux-related  
 13 inflammation and nothing more advanced,  
 14 no other issue. I probably would not  
 15 make a mental note of that or feel the  
 16 need to check something else about that.  
 17 So there are one-and-done  
 18 cases. And there are cases where it's a  
 19 long -- I mean there are patients that  
 20 had been diagnosed and had biopsies for  
 21 ten years.  
 22 Q The vast majority of the  
 23 time where you're doing your pathological  
 24 review, they're one and done; correct?  
 25 MR. SLATER: Objection.

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1 questions, and I will. We'll call  
 2 the judge.  
 3 Q You want to have the  
 4 question read back?  
 5 A Please.  
 6 (The requested portion was  
 7 read back by the court reporter.)  
 8 A Yeah. For the most part,  
 9 that's true. These days in the  
 10 electronic medical record era and people  
 11 having access to their reports, sometimes  
 12 they result themselves online.  
 13 Traditionally and the way it's supposed  
 14 to work is if a physician takes a biopsy  
 15 or does a surgery, that's the physician  
 16 who should be speaking with the patient  
 17 and relaying the results that they got  
 18 from the pathology report.  
 19 Q And that's what I want to  
 20 ask you.  
 21 You're not actually  
 22 conveying diagnoses to the patients;  
 23 correct?  
 24 A Well, as I said, now that  
 25 question has become much more complicated

20 (Pages 74 - 77)

<p>1 to answer than it would have been a 2 couple of years ago before the health 3 apps and that sort of thing. As of now, 4 actually, a lot of patients are getting 5 my report directly. 6 Q You're talking about 7 communications, you and a patient 8 verbally, meeting, discussing, assessing; 9 that happens with a different doctor; 10 correct? 11 A Almost always. 12 Q You're not the one giving 13 cancer diagnosis to the patient; correct? 14 A It depends what you mean by 15 giving. 16 Q Let me fix that. 17 Other than your report, 18 which may have some commentary about the 19 findings, you're not conveying cancer 20 diagnosis in patients; correct? 21 A Well, I would disagree 22 with -- I'm not sure I know exactly what 23 you mean. I would say that when I make a 24 decision of cancer, I have given the 25 diagnosis of cancer for that patient.</p>	<p>Page 78</p> <p>1 with the patient and putting in place the 2 proper care plan. 3 Q Fair enough. 4 So sitting here today, you 5 cannot think of any time -- let me ask it 6 this way. 7 Sitting here today, you have 8 never made a diagnosis in any of your 9 reports that you've done as a pathologist 10 of an NDMA- or NDEA-induced cancer; 11 correct? 12 MR. SLATER: Objection. You 13 could answer. 14 A I don't know. 15 Q Have you ever used those 16 words in a report? 17 A The etiology of a cancer 18 essentially never goes into a report. So 19 even if I diagnose a lung cancer, I don't 20 say lung adenocarcinoma-smoking-related. 21 It's just lung adenocarcinoma. So I 22 couldn't say whether any of the cancers 23 that I've diagnosed have been caused in 24 part or in whole by an NDMA or not. 25 Q Super helpful. Thank you</p>
<p>1 Q You're not in any way 2 verbally communicating or doing anything 3 outside of the report to convey cancer 4 diagnosis to the patient? 5 A That I agree with, yes. 6 Q You expect other doctors -- 7 whether it be, again, surgeons or 8 gastroenterologists or other 9 specialties -- to utilize your report, 10 your findings and then go about meeting 11 with a patient and conveying that to the 12 patient; correct? 13 MR. SLATER: Objection. You 14 can answer. 15 A The only issue I would take 16 with that statement is that often, it's 17 not a surgeon we're relying on. I could 18 be a gastroenterologist. It could be 19 many different members of the care team 20 that are going to be tasked with acting 21 on my report. 22 But I would expect that 23 whoever recorded the procedure that 24 resulted in the issuing of a report, that 25 physician is responsible for interfacing</p>	<p>Page 79</p> <p>1 for saying that. Exactly my point. 2 You don't get into exactly 3 the genesis or cause of the cancer; you 4 just list the cancer in your report or 5 what you think is consistent with cancer; 6 correct? 7 MR. SLATER: Objection. You 8 can answer. 9 A Can you ask the question 10 again? 11 Q Yes. Again, I think you 12 said it. 13 You said in your reports, 14 you put down your findings, not the cause 15 of the findings or the genesis of the 16 findings; correct? 17 MR. SLATER: Objection. You 18 can answer. 19 A I think there are two issues 20 that are getting a little bit conflated 21 here that I want to tease apart. 22 One is, as a pathologist, 23 I'm an expert on pathobiology and 24 pathophysiology. So knowing etiologies 25 of cancer is certainly part of my</p>

1 practice and part of the knowledge base 2 to be a good anatomic pathologist. In an 3 individual case, we usually do not 4 attempt to ascribe an etiology to an 5 individual biopsy sample. 6 Q Let me ask it again. 7 So in your clinical practice 8 when you're preparing your reports, 9 putting down your diagnosis, you don't 10 include etiology is what you're saying; 11 correct? 12 A I may think about the 13 etiology. I may know the etiology. But 14 I very rarely write an etiology in a 15 report. 16 Q And, again, you have never 17 put in any report or any written 18 assessment, pharmaceutical 19 induced-cancer; correct? 20 A I have never used the words 21 "pharmaceutical-induced cancer." 22 Q Or NDMA or NDEA-induced 23 cancer; correct? 24 A Those wouldn't be terms I 25 would put in a report.	Page 82	1 Again, in terms of your 2 analysis or assessment of the specimens 3 you're looking at in any of the cancer 4 diagnosis you've made, you've never in 5 your mind thought, oh, NDEA or NDMA in 6 terms of the etiology? 7 A Correct. In clinical 8 practice, in a busy clinical practice 9 day, that's probably not the sort of like 10 thinking that I would entertain. 11 Q And in terms of the types of 12 cancers that you diagnose, I think you 13 said you diagnose liver cancer from time 14 to time, not diagnosing, you make 15 findings that are consistent with liver 16 cancer; correct? 17 A That's a hair too fine to 18 split. I certainly diagnose many 19 cancers, including liver cancer. I'm a 20 subspecialist in GI and liver cancer. So 21 that means -- or a subspecialist in GI 22 and liver pathology, I should say. So I 23 frequently diagnose cancers of the 24 esophagus, stomach, small intestine, 25 colon, liver, pancreas and bile ducts.	Page 84
1 Q And sitting here today, you 2 can't think of any time when you thought 3 that something was NDMA or NDEA-induced; 4 you can't come up in your mind of any 5 instance where you thought that was the 6 cause or genesis? 7 A I think a patient's exposure 8 history to NDMA is not something that 9 would normally be provided to me. It's 10 not something that would typically enter 11 my thinking. 12 Q That's exactly my point. 13 In your clinical practice, 14 you have never addressed or dealt with 15 the issue of NDEA or NDMA in terms of 16 that being the cause or origin of a 17 cancer; correct? 18 MR. SLATER: Objection. You 19 could answer. 20 Q Or the etiology? 21 MR. SLATER: Objection. You 22 could answer. 23 A Can you ask the question 24 again? 25 Q Yes.	Page 83	1 I also spend three months a year on a 2 general surgery pathology service which 3 exposes me to really almost any type of 4 cancer. But common ones that I see would 5 be breast cancers, lung cancers, cancers 6 of the thyroid gland or head and neck and 7 also prostate, bladder, kidney. 8 Q What percentage of your time 9 of yours is on the surgical rotation? 10 A It can vary a little bit. 11 Usually, it's about a quarter. 12 Q Total time of the year? 13 A Yeah. 14 Q And let me ask this 15 question. 16 As a pathologist -- and I've 17 seen a lot of these reports pathologists 18 make -- when you have a suspicion of 19 cancer of whatever type it is, you don't 20 put down diagnosis of cancer; you put 21 down whatever the finding is consistent 22 with cancer; right? 23 MR. SLATER: Objection. You 24 could answer. 25 A No, not necessarily.	Page 85

22 (Pages 82 - 85)

1 Q You tell me. 2 What verbs do you use? If 3 we were to have access to your reports on 4 your service and they were 5 cancer-related, what is the verb you use? 6 A It depends what sort of 7 cancer that we're talking about. But if 8 we're talking about, say, a colon cancer 9 and it was clearly a cancer, not I'm 10 concerned it's cancer, I know it's 11 cancer, then the diagnosis is invasive 12 adenocarcinoma, then I would give it a 13 degree of differentiation. I would 14 comment on how deeply invasive it is. So 15 that is very clear, a diagnosis of 16 cancer. 17 Q But you're including -- 18 again, the verbiage is talking about the 19 findings; correct? 20 A Well, invasive 21 adenocarcinoma, adenocarcinoma is cancer. 22 That's just a technical way of saying 23 cancer. 24 Q And, again, in terms of any 25 of the times that you are either	Page 86	1 Q If you know about the HPV, 2 is what you're saying? 3 A Well, we can test for it. 4 So testing for it is part of my job. 5 Q So that would be an 6 endogenous etiology; correct? 7 MR. SLATER: Objection. You 8 can answer. 9 A No. It would not be 10 endogenous. It would exogenous from 11 outside. It's the virus. That would be 12 the cause of the cancer. 13 Q And the cigarette smoking, 14 if you're aware of that in the clinical 15 history, you might list that? Do you 16 actually put that in your report? 17 MR. SLATER: Objection. 18 A No, I wouldn't. I would 19 just include the results of HPV testing, 20 negative in that case. 21 Q So that's an example of 22 where you might include an etiology if 23 you're aware of it from a specimen or a 24 test you conduct yourself? 25 MR. SLATER: Objection. You	Page 88
1 suspicious of cancer or listing something 2 that is either a finding of cancer or as 3 you said adenocarcinoma, you never put 4 down etiologies in any of the reports; 5 correct? 6 MR. SLATER: Objection. You 7 could answer. 8 A I wouldn't say never. There 9 are some specific cancers where knowing 10 etiology is actually very important. 11 Q Give me an example. 12 A Sure. So head and neck 13 cancer, for example, especially in the 14 oral cavity. You can get head and neck 15 cancer in the oral cavity from two main 16 ways. One is cigarette smoking. The 17 other is Human Papilloma Virus infection. 18 And I can actually test for HPV 19 infection. And it's important to know 20 whether an oral cancer is HPV-related or 21 not because the HPV ones respond very 22 well to radiation, whereas the smoking 23 and drinking ones don't. So it's 24 standard of care for that cancer to say 25 whether it is or is not caused by HPV.	Page 87	1 can answer. 2 Q Correct? 3 A Yeah, if I do the test 4 myself and if there is a clinical benefit 5 to including that data. 6 Q But other than that -- 7 again, I think you said you won't say 8 never -- but virtually at all times, 9 you're not including an etiology; true? 10 We looked at all your reports? 11 MR. SLATER: Objection. You 12 can answer. 13 A Let me just think for a 14 second. Yeah. I would say in most 15 instances, I do not include an etiology 16 in a report, in most instances. 17 Q And my question was, in 18 virtually all instances other than the 19 one example you came up with, you do not 20 include an etiology? That's not your 21 job; correct? 22 MR. SLATER: Objection. You 23 can answer. 24 A Well, in the liver cancer 25 world, we will often include an etiology	Page 89

<p>1 of the chronic liver cancers, almost      2 always caused by chronic liver disease,      3 be that chronic Hepatitis C, B or      4 alcoholic hepatitis. So we'll almost      5 always include what the background liver      6 disease is. I wouldn't necessarily say      7 hepatocellular carcinoma due to chronic      8 Hepatitis C virus. But I would say      9 hepatocellular carcinoma, moderately      10 differentiated, period; new line, chronic      11 Hepatitis C stage, whatever, et cetera.      12 So a lot of my liver cancers do have an      13 etiology embedded in them.</p> <p>14 Q Yet, never, have you listed      15 a drug or toxicity or impurity as an      16 etiology; true?</p> <p>17 MR. SLATER: Objection. You      18 can answer.</p> <p>19 A I've diagnosed many      20 drug-induced injuries in people. As I      21 sit here today, I don't recall making a      22 diagnosis of a drug-induced cancer or a      23 saying, claiming that some cancer was      24 specifically drug-induced.</p> <p>25 Q And, again, in terms of</p>	<p>Page 90</p> <p>1 that is causing the same histology. So      2 that celiac disease is always a clinical      3 pathologic correlation.</p> <p>4 Contrary, cancer, if I      5 diagnose cancer, there's pretty much      6 nothing that the clinician can tell me      7 that would change my mind about that      8 being cancer.</p> <p>9 Q You're giving your opinion      10 about the findings in the specimen that      11 you look at; true?</p> <p>12 MR. SLATER: Objection. You      13 can answer.</p> <p>14 A Well, I mean if I look at      15 the slide and it's a malignant cancer,      16 then that's what it is. And there's no      17 other explanation for it.</p> <p>18 Q That's what your opinions      19 derive from in your clinical practice,      20 the slides and the specimen; that's what      21 I'm saying; correct?</p> <p>22 MR. SLATER: Objection. You      23 can answer.</p> <p>24 A I'd say that's very narrow.      25 And that's certainly not always the case.</p>
<p>1 treatment -- well, let me ask this.      2 The phrase "clinical      3 pathologic" or "clinical pathology"      4 refers to what you're talking about where      5 it's you and a team of other specialists      6 who are the clinicians following the      7 patient who team up; correct?</p> <p>8 MR. SLATER: Objection. You      9 can answer.</p> <p>10 A The term "clinical      11 pathologic" correlation or "clinical      12 pathologic" diagnosis, what that really      13 is saying is that there are some      14 diagnoses that cannot be made in a vacuum      15 by a pathologist. And there are some      16 that can.</p> <p>17 But, for example, I'm an      18 expert in celiac disease. And I can tell      19 you exactly what celiac disease in the      20 small intestine looks like. But there      21 happen to be a few celiac disease mimics.      22 So I might look at a specimen, and it      23 looks exactly like celiac disease. But a      24 patient actually is not sensitive to      25 gluten. They had a different problem</p>	<p>Page 91</p> <p>1 I think by what you said, there is a sort      2 of cutout of the whole clinical part. It      3 is not a pathologist's job to only do the      4 pathology in a vacuum and ignore the      5 clinical data. There are times when the      6 clinical data is more important than      7 others which is what I was sort of      8 getting at there.</p> <p>9 And the pathologist usually      10 isn't the only one evaluating the      11 clinical data. But, you know, it is --      12 ultimately, if there's anything in the      13 patient's history that I need to know,      14 it's my job to know it.</p> <p>15 Q That's a very important part      16 of what you take into account then;      17 correct?</p> <p>18 MR. SLATER: Objection. You      19 could answer.</p> <p>20 A The patient history?</p> <p>21 Q Yes.</p> <p>22 A Is important.</p> <p>23 Q Patient history, the patient      24 factors in terms of cancer; correct?</p> <p>25 MR. SLATER: Objection. You</p>

<p>1 can answer.</p> <p>2 A As far as diagnosis?</p> <p>3 Q Right.</p> <p>4 A Yes.</p> <p>5 Q And, in fact, one of the</p> <p>6 things when we talked about differential</p> <p>7 diagnosis, that's something that</p> <p>8 obviously you're required to do in your</p> <p>9 clinical practice; correct?</p> <p>10 MR. SLATER: Objection. You</p> <p>11 can answer.</p> <p>12 A Putting together a</p> <p>13 differential diagnosis, a formal</p> <p>14 differential diagnosis, I would include</p> <p>15 it if I think there's doubt about the</p> <p>16 diagnosis.</p> <p>17 Q So you have your report in</p> <p>18 this case, Valsartan. I think it's been</p> <p>19 marked as Exhibit 1 if you pull it up</p> <p>20 there. We'll come back to the deposition</p> <p>21 on some other points later. But you</p> <p>22 could put that aside for now.</p> <p>23 But if you look at</p> <p>24 Exhibit 1, I want to just hone in on page</p> <p>25 3 there. You're familiar with the word</p>	<p>Page 94</p> <p>1 line of questioning anyway that I had not</p> <p>2 explicitly referenced Bradford Hill.</p> <p>3 Q And Mr. Parker questioned</p> <p>4 you about that in your deposition. Do</p> <p>5 you recall that?</p> <p>6 A Vaguely.</p> <p>7 Q And Mr. Slater came back and</p> <p>8 asked you more questions about that. Do</p> <p>9 you recall that?</p> <p>10 A Yes. Vaguely.</p> <p>11 Q Did you ever receive or</p> <p>12 become aware of a Daubert motion that was</p> <p>13 filed? Do you understand what that is?</p> <p>14 A Not entirely.</p> <p>15 Q There was a motion filed to</p> <p>16 exclude you as a witness.</p> <p>17 Did you ever get a copy of</p> <p>18 that?</p> <p>19 A No.</p> <p>20 Q Were you aware of that?</p> <p>21 A I may have been, yes. I</p> <p>22 think I was aware.</p> <p>23 Q In this report in Valsartan,</p> <p>24 you've included specific commentary about</p> <p>25 Bradford Hill?</p>
<p>1 "methodology," of course; right?</p> <p>2 A Yes.</p> <p>3 Q That's something that you do</p> <p>4 in all of your patients; correct?</p> <p>5 A Yes.</p> <p>6 MR. SLATER: Objection.</p> <p>7 A I have a systematic way that</p> <p>8 I approach cases, yes.</p> <p>9 Q And that's something that</p> <p>10 you do in the few expert witness cases</p> <p>11 you were involved in; you know the</p> <p>12 importance of methodology too; correct?</p> <p>13 A Yes.</p> <p>14 Q In your last report,</p> <p>15 Benicar, we had a report and a</p> <p>16 deposition, one thing that was noted was</p> <p>17 that you did not cover in any way, the</p> <p>18 Bradford Hill methodology and</p> <p>19 differential diagnosis in your report;</p> <p>20 correct?</p> <p>21 MR. SLATER: Objection. You</p> <p>22 could answer.</p> <p>23 Q Do you recall that?</p> <p>24 A I recall that being an</p> <p>25 issue, that I had not explicitly -- or a</p>	<p>Page 95</p> <p>1 A Yes.</p> <p>2 Q And was that in response to</p> <p>3 that Daubert motion? Do you know?</p> <p>4 A Well, the Bradford Hill</p> <p>5 viewpoints are kind of standard</p> <p>6 epidemiologic viewpoints that we cover</p> <p>7 when we're in med school learning about</p> <p>8 differences between causation and</p> <p>9 association.</p> <p>10 Now, I did not -- in the</p> <p>11 Benicar report, I did not specifically</p> <p>12 list them out. And that became an</p> <p>13 argument. So for the purposes of not</p> <p>14 getting into the same argument, I listed</p> <p>15 them here. However, there are things I</p> <p>16 would think about. Those are things that</p> <p>17 I thought about in the Benicar litigation</p> <p>18 before producing the report. And there</p> <p>19 are things I think about anytime when</p> <p>20 someone is talking about whether</p> <p>21 something is in association or causative</p> <p>22 relationship.</p> <p>23 Q So you are familiar with</p> <p>24 methodology, differential diagnosis in</p> <p>25 the context of your clinical practice, as</p>
<p>1 can answer.</p> <p>2 A As far as diagnosis?</p> <p>3 Q Right.</p> <p>4 A Yes.</p> <p>5 Q And, in fact, one of the</p> <p>6 things when we talked about differential</p> <p>7 diagnosis, that's something that</p> <p>8 obviously you're required to do in your</p> <p>9 clinical practice; correct?</p> <p>10 MR. SLATER: Objection. You</p> <p>11 can answer.</p> <p>12 A Putting together a</p> <p>13 differential diagnosis, a formal</p> <p>14 differential diagnosis, I would include</p> <p>15 it if I think there's doubt about the</p> <p>16 diagnosis.</p> <p>17 Q So you have your report in</p> <p>18 this case, Valsartan. I think it's been</p> <p>19 marked as Exhibit 1 if you pull it up</p> <p>20 there. We'll come back to the deposition</p> <p>21 on some other points later. But you</p> <p>22 could put that aside for now.</p> <p>23 But if you look at</p> <p>24 Exhibit 1, I want to just hone in on page</p> <p>25 3 there. You're familiar with the word</p>	<p>Page 94</p> <p>1 line of questioning anyway that I had not</p> <p>2 explicitly referenced Bradford Hill.</p> <p>3 Q And Mr. Parker questioned</p> <p>4 you about that in your deposition. Do</p> <p>5 you recall that?</p> <p>6 A Vaguely.</p> <p>7 Q And Mr. Slater came back and</p> <p>8 asked you more questions about that. Do</p> <p>9 you recall that?</p> <p>10 A Yes. Vaguely.</p> <p>11 Q Did you ever receive or</p> <p>12 become aware of a Daubert motion that was</p> <p>13 filed? Do you understand what that is?</p> <p>14 A Not entirely.</p> <p>15 Q There was a motion filed to</p> <p>16 exclude you as a witness.</p> <p>17 Did you ever get a copy of</p> <p>18 that?</p> <p>19 A No.</p> <p>20 Q Were you aware of that?</p> <p>21 A I may have been, yes. I</p> <p>22 think I was aware.</p> <p>23 Q In this report in Valsartan,</p> <p>24 you've included specific commentary about</p> <p>25 Bradford Hill?</p>
<p>1 "methodology," of course; right?</p> <p>2 A Yes.</p> <p>3 Q That's something that you do</p> <p>4 in all of your patients; correct?</p> <p>5 A Yes.</p> <p>6 MR. SLATER: Objection.</p> <p>7 A I have a systematic way that</p> <p>8 I approach cases, yes.</p> <p>9 Q And that's something that</p> <p>10 you do in the few expert witness cases</p> <p>11 you were involved in; you know the</p> <p>12 importance of methodology too; correct?</p> <p>13 A Yes.</p> <p>14 Q In your last report,</p> <p>15 Benicar, we had a report and a</p> <p>16 deposition, one thing that was noted was</p> <p>17 that you did not cover in any way, the</p> <p>18 Bradford Hill methodology and</p> <p>19 differential diagnosis in your report;</p> <p>20 correct?</p> <p>21 MR. SLATER: Objection. You</p> <p>22 could answer.</p> <p>23 Q Do you recall that?</p> <p>24 A I recall that being an</p> <p>25 issue, that I had not explicitly -- or a</p>	<p>Page 95</p> <p>1 A Yes.</p> <p>2 Q And was that in response to</p> <p>3 that Daubert motion? Do you know?</p> <p>4 A Well, the Bradford Hill</p> <p>5 viewpoints are kind of standard</p> <p>6 epidemiologic viewpoints that we cover</p> <p>7 when we're in med school learning about</p> <p>8 differences between causation and</p> <p>9 association.</p> <p>10 Now, I did not -- in the</p> <p>11 Benicar report, I did not specifically</p> <p>12 list them out. And that became an</p> <p>13 argument. So for the purposes of not</p> <p>14 getting into the same argument, I listed</p> <p>15 them here. However, there are things I</p> <p>16 would think about. Those are things that</p> <p>17 I thought about in the Benicar litigation</p> <p>18 before producing the report. And there</p> <p>19 are things I think about anytime when</p> <p>20 someone is talking about whether</p> <p>21 something is in association or causative</p> <p>22 relationship.</p> <p>23 Q So you are familiar with</p> <p>24 methodology, differential diagnosis in</p> <p>25 the context of your clinical practice, as</p>

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<p>1 well as expert work; correct?</p> <p>2 MR. SLATER: Objection. You</p> <p>3 could answer the question.</p> <p>4 A I'm aware that one should</p> <p>5 have a method.</p> <p>6 Q Are you familiar with what</p> <p>7 the other Daubert criteria are? Is that</p> <p>8 legal stuff you don't fully appreciate?</p> <p>9 MR. SLATER: Objection. You</p> <p>10 could answer.</p> <p>11 A I don't know.</p> <p>12 Q One of the things you said</p> <p>13 here on page 3 of your report is, "I am</p> <p>14 basing everything stated herein on the</p> <p>15 basis of the methodology that I apply in</p> <p>16 my clinical and academic work."</p> <p>17 Those were your words;</p> <p>18 right?</p> <p>19 A Yes.</p> <p>20 Q One of the things -- I know</p> <p>21 you just mentioned and we talked about</p> <p>22 before -- is association and causation.</p> <p>23 You agree -- and I'll read this quote --</p> <p>24 "It's a foundational tenet of medical</p> <p>25 science that an association does not</p>	<p>Page 98</p> <p>1 MR. SLATER: Just give me a</p> <p>2 second. Let me get to that. So now</p> <p>3 we're deposing him on the Benicar</p> <p>4 report?</p> <p>5 MS. COHEN: Which exhibit is</p> <p>6 that?</p> <p>7 A 4.</p> <p>8 Q And you actually had a</p> <p>9 section called Methodology and Literature</p> <p>10 in the Benicar report. Do you see that</p> <p>11 on page 2?</p> <p>12 A Okay.</p> <p>13 Q Are you with me on that?</p> <p>14 A I see it.</p> <p>15 Q What you -- I take it again,</p> <p>16 your clinical methodology in 2017 is the</p> <p>17 same as you have now; correct?</p> <p>18 A More or less, yeah.</p> <p>19 Q Nothing has changed about</p> <p>20 that; correct?</p> <p>21 MR. SLATER: Objection. You</p> <p>22 can answer.</p> <p>23 A My clinical methodology?</p> <p>24 Q Yes. We go back to what you</p> <p>25 said here. You said, the basis of the</p>
<p>1 equal causation."</p> <p>2 You agree with that; right?</p> <p>3 MR. SLATER: Objection. You</p> <p>4 can answer.</p> <p>5 A Yes. Certainly, an</p> <p>6 association is not definitive evidence of</p> <p>7 a causation.</p> <p>8 Q And you said that before</p> <p>9 under oath, haven't you?</p> <p>10 A I don't know. But I agree</p> <p>11 with it.</p> <p>12 Q You agree with it.</p> <p>13 So, again, here, Valsartan</p> <p>14 report, you say you're going to use the</p> <p>15 basis and methodology you apply in your</p> <p>16 clinical work; correct?</p> <p>17 MR. SLATER: Objection. You</p> <p>18 can answer.</p> <p>19 A Yes. And I did. I</p> <p>20 consulted Peer Review literature which is</p> <p>21 what I do in clinical work.</p> <p>22 Q Let's look at the Benicar</p> <p>23 report which we marked over there. And I</p> <p>24 think it's that one right there.</p> <p>25 A Okay.</p>	<p>Page 99</p> <p>1 methodology --</p> <p>2 MR. SLATER: Wait. I'm</p> <p>3 sorry. Valsartan or Benicar?</p> <p>4 MS. COHEN: I'm going back</p> <p>5 to Valsartan, page 3 where it says,</p> <p>6 "I'm basing everything stated herein</p> <p>7 on the basis of methodology --</p> <p>8 MR. SLATER: I'm sorry.</p> <p>9 Where are you reading from?</p> <p>10 MS. COHEN: Page 3 of the</p> <p>11 Valsartan report.</p> <p>12 MR. SLATER: Oh. You're in</p> <p>13 the middle of the sentence.</p> <p>14 MS. COHEN: Yes, which we</p> <p>15 read before.</p> <p>16 Q "I'm basing everything</p> <p>17 stated herein on the basis of the</p> <p>18 methodology I apply in my clinical and</p> <p>19 academic work."</p> <p>20 We just read that; right?</p> <p>21 MR. SLATER: Objection. Not</p> <p>22 accurately read.</p> <p>23 A Could you read it again,</p> <p>24 please?</p> <p>25 Q You could take a look. We</p>

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<p>1 just read it before. It's the same 2 sentence. You don't disagree with that, 3 do you?</p> <p>4 MR. SLATER: Objection.</p> <p>5 Q What you said there?</p> <p>6 A I agree with what I said 7 here.</p> <p>8 Q And then if we go back to 9 Benicar, because you had an actual 10 section there a little bit more robust, 11 if you will. So I want to ask you about 12 it.</p> <p>13 What you said there is, "The 14 diagnostic approach I take to such cases 15 is standardized."</p> <p>16 And that's what you said 17 again today; correct?</p> <p>18 MR. SLATER: Objection. You 19 can answer.</p> <p>20 A We're talking about 21 different things here.</p> <p>22 Q Let me read this part.</p> <p>23 MR. SLATER: Were you still 24 talking before counsel interrupted 25 you?</p>	<p>Page 102</p> <p>1 pathologist, what you're doing is looking 2 at specimens; that's what you do; you 3 look at slides, specimens, perhaps some 4 bodies as you said, and that's how you 5 make your determination; correct?</p> <p>6 MR. SLATER: Objection. You 7 can answer.</p> <p>8 A That is the practice of 9 surgical and anatomic pathology.</p> <p>10 Q That's your practice; that's 11 what you do; right?</p> <p>12 MR. SLATER: Objection. You 13 could answer.</p> <p>14 Q Doctor?</p> <p>15 A Yes.</p> <p>16 Q And then when we get to in 17 Benicar in 2016 in your report -- or 18 2017, you said, "The diagnostic approach 19 I take to such cases is standardized, and 20 is the approach utilized in my clinical 21 practice, in connection with the studies 22 I have authored in the Peer-Reviewed 23 medical literature, and presentations 24 given at major professional meetings. I 25 start with the review of very basic,</p>
<p>1 THE WITNESS: Yes.</p> <p>2 MR. SLATER: You could 3 finish your answer.</p> <p>4 A Okay. The Benicar 5 litigation came with a number of actual 6 cases that I investigated at the time. 7 So what I'm describing at least just from 8 a quick overview here is how I would 9 approach a clinical case. So this is 10 not -- I'm sure at some point in getting 11 to review the literature, maybe.</p> <p>12 But at least what I'm seeing 13 here on page 2 is if I received a biopsy 14 from a clinical case, this is the way I 15 would approach it which is the same way I 16 approached the clinical cases that came 17 to me through that litigation. In this 18 litigation, I haven't looked at any 19 specific cases.</p> <p>20 Q I think we agree with all 21 that.</p> <p>22 A Okay.</p> <p>23 Q So let me unpackage that.</p> <p>24 In your clinical practice as 25 an anatomic pathologist or a surgical</p>	<p>Page 103</p> <p>1 clinical information (generally limited 2 to the presenting symptom; e.g. 3 diarrhea). I then begin my slide 4 review;" right?</p> <p>5 A Remains true.</p> <p>6 Q And that is how you do your 7 clinical work; correct?</p> <p>8 MR. SLATER: Objection. You 9 can answer.</p> <p>10 A Yes.</p> <p>11 Q And that's how you do your 12 expert work; correct?</p> <p>13 MR. SLATER: Objection. You 14 could answer.</p> <p>15 A You know, expert work is not 16 one size fits all. So it's different -- 17 I've done expert work where they sent me 18 a slide and say, did the original doctor 19 missed diagnosis of cancer? If that were 20 the case, I would apply the methods 21 specifically listed here which apply to 22 looking at slides and looking at clinical 23 cases. By here, I mean in the page 2 of 24 the Benicar report.</p> <p>25 Part of my practice, though,</p>

<p>1 is also to keep abreast of medical 2 literature and need to produce medical 3 literature. And so if someone were to 4 ask me, as in this case, to look into the 5 issue or issues around NDMA or NDEA, 6 contamination of Valsartan, you know, I 7 wouldn't start looking at a glass slide. 8 I would go to the PubMed. And the 9 methodology I used was a research 10 methodology, essentially, of looking at 11 both statements from regulatory agencies 12 and looking at original Peer Review 13 medical research. And that's the 14 approach I would take if I were writing a 15 paper on a particular topic. Or as new 16 things come up in medicine, that's how I 17 keep abreast.</p> <p>18 Q You obviously never looked 19 at any clinical information, slide 20 reviewed patient information in 21 Valsartan; correct?</p> <p>22 MR. SLATER: Objection. You 23 could answer.</p> <p>24 A That's correct.</p> <p>25 Q And in terms of what you</p>	Page 106	<p>1 A Well, I integrate that 2 information; for example, you know, it 3 would be a pretty lame pathologist who 4 didn't know that cigarette smoking causes 5 lung cancer. And there are more specific 6 examples like the one we talked about 7 with respect to HPV-related cancers of 8 the head and neck.</p> <p>9 But it would be totally 10 inappropriate to Mr. Jones who has a 11 biopsy to get into some treatise on 12 etiology as part of the report on 13 Mr. Jones's cancer. That's not part of 14 my practice.</p> <p>15 Q Right. But that's what I'm 16 saying.</p> <p>17 This answering of a general 18 causation like the one Mr. Slater posed 19 to you that kicks off in your report is 20 not what you do in your clinical 21 practice; true?</p> <p>22 A No. I think that's 23 mischaracterizing it, I think. Every 24 pathologist -- I'm an expert in 25 pathobiology. So pathologists know about</p>	Page 108
<p>1 just described, what you described 2 before, answering a general question of 3 general causation of cancer in humans, 4 you've never done that as part of your 5 clinical practice, have you?</p> <p>6 MR. SLATER: Objection. You 7 could answer.</p> <p>8 A Sorry. What is the 9 question?</p> <p>10 Q Yes.</p> <p>11 When you go through the 12 pathology evidence that you do in your 13 cases as part of your clinical practice, 14 you're obviously looking at data, 15 clinical data slides, patient 16 information; correct?</p> <p>17 A Yes.</p> <p>18 Q You've never in terms of 19 your clinical practice answered a general 20 causation question like the one that 21 Mr. Slater put to you that kicks off your 22 expert report; correct?</p> <p>23 MR. SLATER: Objection. You 24 could answer.</p> <p>25 Q It's not what you do?</p>	Page 107	<p>1 the causative factors of cancers and 2 inflammatory illnesses. It's a major 3 part of that. But it doesn't go in a 4 report, usually. But not going in a 5 report is different from not using that 6 information or knowing that information.</p> <p>7 Q Let me ask a couple of 8 follow-up questions.</p> <p>9 You agree you don't put that 10 in the report; correct?</p> <p>11 MR. SLATER: Objection. You 12 can answer.</p> <p>13 Q You just said it.</p> <p>14 A In most instances.</p> <p>15 Q You agree you don't put it 16 in the report in most instances; correct?</p> <p>17 A Correct.</p> <p>18 Q You haven't written any 19 papers about it; correct?</p> <p>20 MR. SLATER: Objection. You 21 can answer.</p> <p>22 A About causation?</p> <p>23 Q Yes.</p> <p>24 General causation of cancer 25 like we have in this case, you've never</p>	Page 109

<p>1 written a paper on that topic; true?</p> <p>2 A No. I don't think that's</p> <p>3 true.</p> <p>4 Q You're welcome to tell me</p> <p>5 which ones are general causation</p> <p>6 literature.</p> <p>7 A Give me a moment, please, to</p> <p>8 review. Reference 7.</p> <p>9 Q Van Treeck, is that the one?</p> <p>10 A Yes.</p> <p>11 Q And that's the</p> <p>12 hepatocellular carcinoma, reveals novel</p> <p>13 distinct biological features?</p> <p>14 A Yes.</p> <p>15 Q And you believe that is a</p> <p>16 general causation article?</p> <p>17 A Yes.</p> <p>18 Q We have it. And I'm happy</p> <p>19 to discuss it with you later.</p> <p>20 What else?</p> <p>21 A 12.</p> <p>22 Q Metastatic breast cancer</p> <p>23 revealed by a systematic analysis.</p> <p>24 A Enrichment of kinase fusions</p> <p>25 in the SR wild-type, yeah, that deals</p>	<p>Page 110</p> <p>1 specific causation? I'm happy to explain</p> <p>2 it to you.</p> <p>3 A I certainly have thoughts on</p> <p>4 that. But let me hear how you're</p> <p>5 interpreting it first.</p> <p>6 Q I think specific causation</p> <p>7 would be a situation where you're</p> <p>8 assessing medical records, clinical</p> <p>9 features, specific data points, specific</p> <p>10 pathological information.</p> <p>11 A Okay.</p> <p>12 Q Like you describe in your</p> <p>13 Benicar report.</p> <p>14 Isn't that what this article</p> <p>15 with the 4,854 patients is?</p> <p>16 MR. SLATER: Objection.</p> <p>17 Q Specific issues of patients?</p> <p>18 MR. SLATER: Objection. You</p> <p>19 can answer.</p> <p>20 A It's pathobiology of cancer.</p> <p>21 Q Any other articles that --</p> <p>22 the question that I posed to you is, have</p> <p>23 you written about general causation of</p> <p>24 cancer?</p> <p>25 MR. SLATER: Objection. You</p>
<p>1 with causation of cancer.</p> <p>2 Q Do you believe that that is</p> <p>3 an opinion on general causation like the</p> <p>4 type that was framed in this case to you</p> <p>5 by Mr. Slater?</p> <p>6 MR. SLATER: Objection. You</p> <p>7 can answer.</p> <p>8 A I'm giving you papers that</p> <p>9 I've been involved in dealing with</p> <p>10 causation of cancer.</p> <p>11 Q Right. Let me ask.</p> <p>12 12 is about 4,854 patients</p> <p>13 that addresses a specific patient like</p> <p>14 the clinical findings we're talking</p> <p>15 about, like the methodology that's in the</p> <p>16 Benicar. There are patients here; right?</p> <p>17 MR. SLATER: Objection. You</p> <p>18 could answer.</p> <p>19 Q Mr. Slater likes to laugh at</p> <p>20 every question. So I assume that doesn't</p> <p>21 bother you. Doesn't bother me either.</p> <p>22 A I'm afraid I don't totally</p> <p>23 understand where we're --</p> <p>24 Q Do you understand the</p> <p>25 difference between general causation and</p>	<p>Page 111</p> <p>1 can answer.</p> <p>2 Q Can this etiology cause this</p> <p>3 type of cancer?</p> <p>4 A Well, yeah. I mean No. 12</p> <p>5 certainly is satisfactory there.</p> <p>6 Q You think 7 is too, the one</p> <p>7 we pointed to first?</p> <p>8 A Possibly.</p> <p>9 Q Not sure, but maybe?</p> <p>10 A It could be argued, one way</p> <p>11 or the other.</p> <p>12 Q It might be.</p> <p>13 A We can do that. 12 is; 14;</p> <p>14 17; 19 is related to causation of</p> <p>15 neoplasia, non-malignant neoplasia; 21;</p> <p>16 29; No. 6 under case reports.</p> <p>17 Q Does that involve a patient?</p> <p>18 A Yes.</p> <p>19 Q So that wouldn't be</p> <p>20 case-specific as opposed to general</p> <p>21 commentary on causation?</p> <p>22 A Well, I mean -- generally,</p> <p>23 any case report is published because the</p> <p>24 thought is, it might be generalizable at</p> <p>25 least to other patients.</p>

<p>1 Q You understand what 2 epidemiology is; right?</p> <p>3 A Yes.</p> <p>4 Q And you're not an 5 epidemiology expert, are you?</p> <p>6 MR. SLATER: Objection. You 7 can answer.</p> <p>8 A So are we putting aside the 9 last question?</p> <p>10 Q No. I'll re-ask it in a 11 minute.</p> <p>12 A Okay. No. 6 on selected 13 published abstracts.</p> <p>14 Q Have you gone back and read 15 any of these before today?</p> <p>16 A Any of my papers?</p> <p>17 Q Yes. The ones that you're 18 looking at now.</p> <p>19 A Okay. I think that covers 20 that.</p> <p>21 Q Any other business where 22 you've written about or published about 23 general causation, like a question that 24 was posed in this case, and you listed 25 the ones that you think are part of that?</p>	<p>Page 114</p> <p>1 Q I didn't ask you about -- I 2 asked you about general causation.</p> <p>3 What I mean by that is, in 4 this case, what you told me a little 5 while ago is that you didn't look at any 6 patient-specific information, no medical 7 records, no slides, which is what you do 8 in your normal practice; correct?</p> <p>9 MR. SLATER: Objection. You 10 can answer.</p> <p>11 A I didn't look at any 12 specific patient data, correct.</p> <p>13 Q And the articles you cited 14 to me, at least some of them, look at 15 patient-specific data?</p> <p>16 A I don't see how the fact 17 that they might have used specific 18 patients as a basis for their 19 conclusions, how that would relate to 20 whether or not a conclusion is 21 generalizable or not.</p> <p>22 For example, saying that we 23 looked at 4,000 patients and we found 24 X percent had this mutation and we think 25 this maybe driving their cancer, that is</p>
<p>1 MR. SLATER: Objection. 2 Foundation. You can answer.</p> <p>3 A Yeah. I answered with 4 respect to Peer Review publications that 5 I've authored or coauthored that deal 6 with the issue of causation of cancer.</p> <p>7 Q My question was about 8 general causation. You remember that; 9 right?</p> <p>10 MR. SLATER: Objection.</p> <p>11 A Yeah. I'm not sure, you 12 know, where -- anything I've published is 13 because I would expect it to be 14 generalizable, at least to some extent.</p> <p>15 Q And just because this will 16 be part of the record later, you 17 understood my question --right?-- when I 18 asked you?</p> <p>19 MR. SLATER: Objection.</p> <p>20 A I answered it to the best of 21 my understanding. I understood 22 something. I answered that thing. That 23 is not what you asked, then I didn't 24 understand you. If that was what you 25 asked, then I did.</p>	<p>Page 115</p> <p>1 pathobiology of cancer, that's causation 2 of cancer. And presumably, those are not 3 the only patients on earth with that 4 situation.</p> <p>5 Q That's an important part of 6 your analysis; that is what happened in 7 those patients; correct?</p> <p>8 A Those patients provided the 9 basis of the analysis that took place.</p> <p>10 Q Other than this report that 11 we've marked as Exhibit 1 in this case, 12 have you ever rendered a causation 13 opinion based purely on articles and 14 general information without patient 15 information as an anatomic pathologist 16 that you are?</p> <p>17 MR. SLATER: Objection. You 18 can answer.</p> <p>19 A Could you repeat that?</p> <p>20 Q I'll try it again.</p> <p>21 Never once in real life, not 22 in a litigation, have you rendered a 23 causation opinion based purely on 24 articles and not with regard to patients?</p> <p>25 MR. SLATER: Objection. You</p>

<p>1 can answer.</p> <p>2 A I base opinions on causation</p> <p>3 strictly from articles many times. But I</p> <p>4 have not written a report to that effect.</p> <p>5 Q So what I said was true?</p> <p>6 You never rendered an official causation</p> <p>7 opinion based on articles without regard</p> <p>8 to patients?</p> <p>9 MR. SLATER: Objection. You</p> <p>10 can answer.</p> <p>11 Q And patient information.</p> <p>12 A Well, I mean without</p> <p>13 regard -- this is all -- I'm a doctor.</p> <p>14 So, of course, I'm thinking about how</p> <p>15 this would impact a patient. That's the</p> <p>16 framing that I used to understand this</p> <p>17 problem, is, would this do something or</p> <p>18 nothing to a patient. And if so, would</p> <p>19 that be a good, bad or neutral thing.</p> <p>20 Q I asked the question, never</p> <p>21 once in real life, not in litigation have</p> <p>22 you rendered a causation opinion based</p> <p>23 purely on articles and not with regard to</p> <p>24 patients. And you said I have not</p> <p>25 written a report to that effect; correct?</p>	<p>Page 118</p> <p>1 all that in a minute.</p> <p>2 But my question again is,</p> <p>3 this is the first time you've done this,</p> <p>4 that is rendered an official opinion like</p> <p>5 this without looking at patient</p> <p>6 information?</p> <p>7 MR. SLATER: Objection.</p> <p>8 Foundation. You can answer.</p> <p>9 A I mean I definitely looked</p> <p>10 at patient information. All the</p> <p>11 epidemiologic studies deal with patient</p> <p>12 information. I just didn't look at my</p> <p>13 own data. I didn't treat any of these</p> <p>14 patients.</p> <p>15 Q That's not what you do in</p> <p>16 real life, is it?</p> <p>17 MR. SLATER: Objection.</p> <p>18 A In real life?</p> <p>19 Q As a doctor, as a clinical</p> <p>20 pathologist, an anatomic pathologist, you</p> <p>21 do not do what you did in this case;</p> <p>22 true?</p> <p>23 MR. SLATER: Objection. You</p> <p>24 could answer.</p> <p>25 A Well, I read literature of</p>
<p>1 MR. SLATER: Objection. You</p> <p>2 can answer.</p> <p>3 Q Is that what you said?</p> <p>4 A Not that I could think of at</p> <p>5 this moment.</p> <p>6 Q So I took it one step</p> <p>7 further.</p> <p>8 You've never given an</p> <p>9 official causation opinion, report or</p> <p>10 otherwise, based purely on general</p> <p>11 articles without patients and patient</p> <p>12 information?</p> <p>13 MR. SLATER: Objection. You</p> <p>14 can answer.</p> <p>15 A Sure. I mean it's not on</p> <p>16 general articles. It's on specific</p> <p>17 articles that did look at patients</p> <p>18 largely and also experimental animals.</p> <p>19 Those are the reliances that were</p> <p>20 provided and are included here. That's</p> <p>21 the basis of my opinion, Peer Review</p> <p>22 medical literature, as well as guidelines</p> <p>23 and consensus statements from World</p> <p>24 Health Organization, IARC, FDA.</p> <p>25 Q We're going to go through</p>	<p>Page 119</p> <p>1 this type in my daily practice. It's</p> <p>2 important for me as I said to know</p> <p>3 etiologies and to know causation. So</p> <p>4 reading these things, forming opinions is</p> <p>5 all very much part of what I do.</p> <p>6 As far as making an official</p> <p>7 report, I mean that doesn't go into a</p> <p>8 patient report. In the literature that I</p> <p>9 write, I might include things that I</p> <p>10 found, and I certainly do include things</p> <p>11 that were found in the Peer Review</p> <p>12 literature, some of which I can't off the</p> <p>13 top of my head mention every -- you know,</p> <p>14 every citation included in any of my</p> <p>15 research.</p> <p>16 But, you know, the</p> <p>17 discussion portions or the introduction</p> <p>18 portions of a research paper often</p> <p>19 summarize literature similar to what's</p> <p>20 done in this report. Now, there probably</p> <p>21 are some patients that I encountered also</p> <p>22 in that Peer Review literature. So if</p> <p>23 you want to draw some -- draw some</p> <p>24 bright line there, I'm not sure that it</p> <p>25 really is applicable. But I don't</p>

<p>1 think -- you know, I haven't produced a 2 document like this outside of this. 3 Q This is the first time in 4 this litigation; correct? 5 MR. SLATER: Objection. You 6 can answer. 7 A Yeah. I've dealt with the 8 issue of causation in other contexts but 9 not as a stand-alone. 10 Q And I think I asked you this 11 before. 12 You certainly do not hold 13 yourself out as an epidemiologist; 14 correct? 15 A Again, I understand 16 epidemiology. I learned epidemiology in 17 medical school. I am aware of 18 epidemiologic concepts. And I've worked 19 with and published with epidemiologists. 20 Q Have you ever said under 21 oath that you certainly do not hold 22 yourself out as an epidemiologist? 23 A I do not know. I am not a 24 professional epidemiologist per say. I 25 am familiar with it.</p>	<p style="text-align: right;">Page 122</p> <p>1 about. 2 Q And you understand the 3 importance as an expert witness of being 4 honest and unbiased and not being an 5 advocate; correct? 6 A Yes. 7 (The above-referred-to 8 document was marked as Exhibit 7 for 9 identification, as of this date.) 10 Q And here is Exhibit 7, which 11 I'll give you. And this is -- 12 MR. SLATER: A different 13 version that I have. Oh. You just 14 put the sticker on it. Got it. No 15 problem. 16 Q On this one, just going back 17 to page 342 on this epidemiology -- 18 MR. SLATER: Just one 19 question, counsel. I'm just not sure 20 and I don't remember because the 21 Benicar litigation was several years 22 ago. But this is marked as protected 23 information, this transcript. So I 24 just want to make sure -- I'm not 25 sure how you got this or whether or</p>
<p>1 Q Let's go ahead and mark this 2 one as an exhibit too. 3 And while we're getting that 4 out, you're a member of CAP? 5 A Yes. 6 Q You've been a member for how 7 many years? 8 A I don't remember. Maybe 9 ten. 10 Q You're familiar with their 11 expert witness guidelines? 12 A I don't know that I've seen 13 them. 14 Q Regardless, I'm sure that 15 you would agree as an expert witness, you 16 should only venture into areas where 17 you're qualified; correct? 18 A Yes. 19 Q You would not again offer 20 opinions in areas where you're not 21 qualified or it's outside of the realm of 22 what you know and do in your practice; 23 correct? 24 A Well, I wouldn't offer 25 opinions outside of things that I know</p>	<p style="text-align: right;">Page 123</p> <p>1 not there was any violation of the 2 protective order in the Benicar 3 litigation. 4 MS. COHEN: I think it was 5 filed. 6 MR. SLATER: It was attached 7 to the Daubert motion? 8 MS. COHEN: I think so. 9 MR. SLATER: I think Susan 10 Sharko might not be excited if 11 confidential or protective 12 information is being put on the 13 record. 14 MS. COHEN: I'll state on 15 the record, it's online, publicly 16 available. 17 MR. SLATER: Perfectly fine. 18 Just looking out for everyone's 19 interests. 20 Q Page 342? 21 MR. SLATER: 342? 22 MS. COHEN: Yes. 23 MR. SLATER: Just give me a 24 second to turn to that page. 25 Q And the question was on line</p>

<p>1 2, "You certainly don't hold yourself out 2 as an epidemiologist?" 3 And what did you say back 4 then under oath? 5 A "I do not." 6 Q And you said as far as being 7 a part of the College of American 8 Pathologists, you're not familiar with 9 the expert witness guidelines? 10 A Not that I recall. 11 Q Would you say you agree with 12 the points of -- 13 MR. SLATER: If you're 14 reading from something -- 15 MS. COHEN: No. I'm going 16 to ask if he understands this. 17 MR. SLATER: So you're not 18 going to show him the document that 19 he's not familiar with? 20 MS. COHEN: Right. 21 MR. SLATER: You're just 22 going to read from it? 23 MS. COHEN: Yes. 24 MR. SLATER: I don't have 25 it. So I can't verify what you're</p>	<p>Page 126</p> <p>1 identification, as of this date.) 2 MS. COHEN: These are the 3 ones that counsel for plaintiffs have 4 provided to us. We'll mark them as a 5 composite exhibit. 6 MR. SLATER: This will be 7 Exhibit 8, I guess, the invoices? 8 MR. SANJABI: It is, yes. 9 THE VIDEOGRAPHER: We are 10 now going off the record. The time 11 is 11:41 a.m. Eastern Time. 12 (A short recess was taken.) 13 THE VIDEOGRAPHER: We are 14 now back on the record. The time is 15 11:57 a.m. Eastern Time. 16 MS. COHEN: So we're back 17 on. And we'll shoot to get to the 18 next part. We're going to take a 19 break at one o'clock for everybody so 20 they know that's coming. And I did 21 pull out the invoices while on the 22 break. And I think we have them all 23 together now. 24 Q Let's see. Exhibit 8, I'll 25 give that to you.</p> <p>Page 127</p> <p>1 saying is accurate. 2 MS. COHEN: No. My 3 questions are just in general. I 4 want to just ask him whether he 5 agrees with this statement. 6 Q That an expert witness 7 should possess current experience and 8 ongoing knowledge in the area in which 9 you're testifying. You agree with that? 10 A Yes. 11 Q You agree that as an expert, 12 you should testify fairly -- as fairly 13 and objectively as possible? 14 A Definitely. 15 Q And as an expert witness, do 16 you agree that you should review the 17 facts in a thorough, fair and objective 18 manner and not exclude any relevant 19 information? 20 A I do. 21 Q Now, we talked about before 22 that -- and we have your invoices which 23 we can go ahead and mark as an exhibit. 24 (The above-referred-to 25 document was marked as Exhibit 8 for</p>	<p>Page 128</p> <p>1 identification, as of this date.) 2 MS. COHEN: These are the 3 ones that counsel for plaintiffs have 4 provided to us. We'll mark them as a 5 composite exhibit. 6 MR. SLATER: This will be 7 Exhibit 8, I guess, the invoices? 8 MR. SANJABI: It is, yes. 9 THE VIDEOGRAPHER: We are 10 now going off the record. The time 11 is 11:41 a.m. Eastern Time. 12 (A short recess was taken.) 13 THE VIDEOGRAPHER: We are 14 now back on the record. The time is 15 11:57 a.m. Eastern Time. 16 MS. COHEN: So we're back 17 on. And we'll shoot to get to the 18 next part. We're going to take a 19 break at one o'clock for everybody so 20 they know that's coming. And I did 21 pull out the invoices while on the 22 break. And I think we have them all 23 together now. 24 Q Let's see. Exhibit 8, I'll 25 give that to you.</p> <p>Page 129</p> <p>1 A Okay. 2 Q I'll just tell you, Doctor, 3 that counsel provided these to us as all 4 of the invoices to date. So I just want 5 to have you confirm that. And then I'll 6 ask you a few questions as well. 7 A Yes. This looks like 8 everything that I've billed to date. 9 Q And this shows us -- again, 10 I know the date on the first page, 11 although you can't see it here, I think 12 when we pulled it up electronically was 13 2020. Is that your understanding as 14 well? 15 A Yes. 16 Q And I think we know from our 17 discussion before in Benicar, you did 18 your report I believe in 2016, and at 19 your deposition in 2017. I want to make 20 sure those dates are correct. Does that 21 sound right? 22 A Sounds generally right. I 23 don't recall specifically. 24 Q November 30th, 2016 was the 25 report. And then we have the deposition</p>
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<p>1 taken in 2017, February 7th, 2017. 2 So, again, this is now just 3 a few years later. An hour discussion 4 with Mr. Slater kind of kicked things off 5 in August 2012. You agree with that? 6 A Sounds right. 7 Q In terms of the rates, I 8 think you clarified that the rate was 9 \$600 an hour; is that correct? 10 A That is. 11 Q And that's for all review 12 information, review of everything; in the 13 deposition, you charge \$5,000 a day? 14 A \$6,000 per day. 15 Q In the Benicar report on 16 page 2, which I believe is Exhibit 4, 17 let's see, your compensation at that time 18 was \$500 an hour. So that's gone up 19 \$100; is that right? My sophisticated 20 math. 21 A If that's what it says here, 22 then, yes, it's gone up. 23 Q Page 2, looks like that's 24 increased by 100. I thought it was going 25 to be a very significant increase going</p> <p>1 from \$1,000 about an hour for testimony 2 to about \$5,000 per hour. 3 A Yeah. It's not that much. 4 Yeah. 5 Q It's gone up, though? 6 A It's gone up, as does 7 everything. 8 Q You said here back in 2017 9 that you have not previously testified at 10 court or in deposition at any lawsuit. 11 So was it at that time that 12 you had not given any testimony at all? 13 A Right. 14 Q Are you doing anything to 15 advertise your availability or 16 willingness to do expert witness work? 17 A I think I might have signed 18 up for one or two directories. 19 Q And was that like SEAK? Is 20 that one of them? 21 A I don't know. To be honest, 22 I haven't gotten any referrals for many 23 years. I don't recall. 24 Q How did you and Mr. Slater 25 first meet?</p>	<p>Page 130</p> <p>1 A I think Mr. Slater knew one 2 of my colleagues. And he was looking for 3 a pathologist. And I was recommended. 4 Q And then you got involved in 5 the Benicar litigation? 6 A Yeah. 7 Q And that litigation -- 8 again, the Benicar litigation had to do 9 with, would you agree -- let me ask you. 10 What do you think it had to 11 do with, the Benicar litigation? 12 MR. SLATER: Objection. You 13 can answer. 14 A Some percentage of patients 15 who take Benicar and other sartans. But 16 mainly, Benicar, have a terrible reaction 17 to it where they get diarrhea, 18 malabsorption, they lose tons of weight, 19 many of them end up hospitalized with 20 dehydration from all the diarrhea. So 21 really, a terrible celiac-like illness 22 that thankfully seems to be away 23 relatively quickly when they stop taking 24 the drug. 25 Q And celiac disease, celiac</p> <p>Page 131</p> <p>1 disease research is one of your primary 2 areas of research; correct? 3 A Yes. 4 Q And, in fact, in the report, 5 you talk about how celiac is one of your 6 areas of focus, and inflammatory 7 conditions of the small intestine are 8 also one of your major research 9 interests; correct? 10 A Definitely. 11 Q And that's still true; 12 right? 13 A Absolutely. 14 Q Now, this has -- let's 15 see -- you're billing up to the date of 16 the report, July 6th? 17 A Correct. 18 Q How much time have you spent 19 since the report? An estimate is fine. 20 A 15 hours. 21 Q Getting ready for today? 22 A Yes. 23 Q And what did you 24 specifically do to get ready for today? 25 A I re-read my report, perhaps</p>
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<p>1 more than once. I re-read key literature 2 studies.</p> <p>3 Q Are those some of the ones 4 you have here on the table?</p> <p>5 A In the -- yeah.</p> <p>6 Q If they're key, you'd have 7 them here on the table; is that right?</p> <p>8 A I believe so, yeah.</p> <p>9 Q And we'll probably get those 10 marked or at least identify them before 11 the end of the day.</p> <p>12 A Okay.</p> <p>13 MR. SLATER: Objection to 14 the form of the question. I didn't 15 want to talk over you.</p> <p>16 THE WITNESS: Okay.</p> <p>17 A So, yeah, reviewed my 18 report, reviewed my literature or the 19 literature that I had collected as part 20 of my research, had some discussions with 21 Mr. Slater.</p> <p>22 Q Did you get together to 23 meet?</p> <p>24 A No.</p> <p>25 MR. SLATER: You mean in</p>	<p>Page 134</p> <p>1 A No.</p> <p>2 Q You didn't seek any 3 information from any colleagues?</p> <p>4 A No.</p> <p>5 Q There's an oncology group at 6 Columbia; right?</p> <p>7 A Yes.</p> <p>8 Q And are they people that you 9 consult with on patients?</p> <p>10 A Yes.</p> <p>11 Q They treat patients; 12 correct?</p> <p>13 A Yes.</p> <p>14 Q Terrible question.</p> <p>15 On the patients for whom you 16 write your pathology reports, the 17 oncologists would be involved to treat 18 the patients; correct?</p> <p>19 MR. SLATER: Objection. You 20 can answer.</p> <p>21 A If it's a patient that 22 requires oncologic medicines. If they 23 need surgery, they might go to a surgeon 24 instead.</p> <p>25 Q Are there particular ones</p>
<p>1 person?</p> <p>2 MS. COHEN: It's not that 3 important.</p> <p>4 Q Do you talk by phone?</p> <p>5 A We talked by phone.</p> <p>6 Q And today, you two walked in 7 together.</p> <p>8 That was just a coincidence?</p> <p>9 A I saw him pull into the 10 parking lot and said hi.</p> <p>11 Q How much in total, how many 12 hours have you spent? Do you know?</p> <p>13 A No.</p> <p>14 Q How much time have you spent 15 on your report itself, that is writing 16 it?</p> <p>17 A I think most of the last 18 bill was spent writing the report. So 19 that would be 33 and a half hours. I 20 didn't -- some of this, other than the 21 December bill, could have been 22 report-related, or it could have been 23 literature review-related.</p> <p>24 Q Did you have to consult with 25 anybody about any issues or questions?</p>	<p>Page 135</p> <p>1 that you collaborate on patients or does 2 that just happen just some other way?</p> <p>3 A It's kind of luck of the 4 draw, I would say. Maybe not luck. I 5 don't have a specific relationship, 6 whereas some oncologists, you know, 7 specifically refers to me or vice versa.</p> <p>8 Q You don't hold yourself out 9 as an oncologist; correct?</p> <p>10 A No.</p> <p>11 Q And there's nowhere we could 12 look online, either with the expert 13 witness groups that you signed up for or 14 Web sites or anywhere on the Columbia Web 15 site that says you're a cancer 16 specialist; correct?</p> <p>17 MR. SLATER: Objection. You 18 can answer.</p> <p>19 A So there are some people who 20 refer to the surgical pathology of cancer 21 as oncologic pathology. And certainly, I 22 am an oncologic pathologist. I'm an 23 expert in pathology of cancer and 24 pathobiology of cancer. Oncologists, 25 medical oncologists, I say medical</p>

<p>1 oncologists because this would refer to a 2 radiation or surgical oncologist. But a 3 medical oncologist is an expert at the 4 drug regimens that are given to patients 5 with cancer. So that, I am certainly 6 not. I have a little bit of knowledge 7 there. But I am not a medical 8 oncologist. You could say I'm an 9 oncologic pathologist.</p> <p>10 Q So I understand that you 11 think you have -- you consider yourself 12 to have in the field of pathology, 13 expertise in cancer?</p> <p>14 A Yes.</p> <p>15 Q And that's what you said 16 already today. I'm not going to argue 17 with you about that, nor am I going to 18 agree with you on that. It's a fact. 19 And we'll leave it alone.</p> <p>20 But is there anywhere that 21 you've held yourself out publicly to the 22 world on a Web site as an expert witness, 23 anything where you say I'm a cancer 24 expert?</p> <p>25 MR. SLATER: Objection. You</p>	<p>Page 138</p> <p>1 be. As far as expert on cancer, I mean I 2 certainly am. I'm an expert in the 3 diagnostics of cancer, pathobiology of 4 cancer.</p> <p>5 Q And, again --</p> <p>6 A Et cetera.</p> <p>7 Q Are you finished?</p> <p>8 A Yes.</p> <p>9 Q So I basically said we're 10 not going to argue about that.</p> <p>11 What I'm asking you is, is 12 there anywhere you've held yourself out 13 on a Web site, publicly as someone who 14 has expertise in cancer or oncology?</p> <p>15 MR. SLATER: Objection. You 16 can answer it again.</p> <p>17 MS. COHEN: Well, he keeps 18 changing the answer.</p> <p>19 MR. SLATER: Counsel, you're 20 getting argumentative.</p> <p>21 MS. COHEN: I'm not.</p> <p>22 MR. SLATER: Well, you know 23 what, counselor, you are. And I 24 don't think you're listening to his 25 answers.</p>
<p>1 can answer.</p> <p>2 A Well, I'm definitely an 3 expert on cancer diagnostics.</p> <p>4 Q But --</p> <p>5 A And cancer biology.</p> <p>6 MR. SLATER: Can you please 7 let him finish?</p> <p>8 Q I already said --</p> <p>9 MR. SLATER: Counsel, you're 10 doing it again. Please let him 11 finish his answers.</p> <p>12 A Whether it says on my 13 faculty Web site or something, those 14 words, I don't know.</p> <p>15 Q That's what I'm asking you.</p> <p>16 A I don't know.</p> <p>17 Q Is there anywhere in the 18 world that you hold yourself out as 19 either having a special expertise of 20 cancer oncology?</p> <p>21 A I think we're maybe getting 22 a little confused about medical oncology 23 versus cancer in general. So medical 24 oncology, again, I am not a medical 25 oncologist. And I would never claim to</p>	<p>Page 139</p> <p>1 MS. COHEN: No. I am.</p> <p>2 MR. SLATER: So you're 3 withdrawing the last question?</p> <p>4 MS. COHEN: Yes.</p> <p>5 Q I'm asking you again, is 6 there anywhere -- it's the same question, 7 but you keep changing the direction.</p> <p>8 MR. SLATER: Counsel, that's 9 the third time --</p> <p>10 MS. COHEN: Do you want to 11 call --</p> <p>12 MR. SLATER: No. I'm just 13 asking you not to be argumentative 14 with him. I think I've been very 15 polite today. I don't think your 16 suggesting that I'm not being polite 17 is fair.</p> <p>18 MS. COHEN: I'm not always 19 fair. But I try to be.</p> <p>20 Q Is there anywhere that 21 you've held yourself out publicly on a 22 Web site or in advertising or anywhere 23 else as having cancer oncology expertise?</p> <p>24 MR. SLATER: Objection. You 25 could answer.</p>

<p style="text-align: right;">Page 142</p> <p>1 A I don't know. Maybe. 2 Q Now, in the expert witness 3 groups that you've now signed up for, how 4 many of them are there? 5 A I don't know; two, maybe. 6 Q And you don't remember the 7 names of them? 8 A Correct. 9 Q You're listed as part of 10 them to offer up your expert services? 11 A Correct. 12 Q Could you provide the names 13 of the companies to Mr. Slater after 14 since you can't remember them now 15 following this event today? 16 A I don't know. 17 Q Do you get paid by them? 18 A If I recall correctly, I 19 might have been referred one case through 20 one of them many years ago. And in which 21 case, I would -- I don't know if they 22 paid me or whoever hired me paid me. 23 Certainly not in recent memory, have I 24 gotten a case from them. So I'm just not 25 sure I could produce that information.</p>	<p style="text-align: right;">Page 144</p> <p>1 A May I review what the Web 2 site says? 3 Q Yes. 4 A Okay. So the Columbia web 5 site says I'm a surgical pathologist. 6 And surgical pathologists are an expert 7 at cancer -- and that is a fact -- where 8 the cancer diagnosticians with 9 subspecialty expertise in GI and 10 pathology. And that would encompass 11 inflammatory and malignant neoplasms. 12 And then if you go to the 13 next page, page 4, it does include liver 14 tumors as an area of expertise and also 15 hepatocellular carcinoma. 16 Q Liver cancer? 17 A Liver cancer. 18 Q Does it say anywhere 19 cancers? 20 MR. SLATER: Can you let him 21 finish, please? 22 A It doesn't list other 23 cancers. But as I said, I'm a 24 subspecialist in GI pathology. So GI 25 neoplasms, their biology, their</p>
<p style="text-align: right;">Page 143</p> <p>1 Q Do you know what you listed 2 yourself as in those groups? Do you list 3 yourself as a pathology expert? 4 A Probably, yes. I would 5 assume so. I don't remember. 6 Q And is it fair to say that 7 you do not list yourself as a cancer 8 expert? 9 MR. SLATER: Objection. You 10 can answer. 11 A I wouldn't say that that's 12 fair. I mean I am an expert on cancer 13 diagnostics, pathobiology of cancer. At 14 least, you know, a good portion of my 15 time is spent diagnosing cancer, staging 16 cancer. As I mentioned before, working 17 on the proper ancillary tests to do for 18 patients with cancer. So I certainly do 19 not think it is in any stretch, in any 20 way a stretch to say that I'm not an 21 expert on cancer. 22 Q Why doesn't the Columbia Web 23 site call you an expert on cancer? 24 MR. SLATER: Objection. You 25 can answer.</p>	<p style="text-align: right;">Page 145</p> <p>1 diagnostics, their prognosis, there's 2 staging, there's theranostics, meaning 3 what markers they express that might 4 guide treatment. I'm damn sure an expert 5 on all of that. And I'm not going to, 6 you know, negotiate that word. 7 Q Liver is what you're saying? 8 MR. SLATER: Objection. 9 A No. Liver, GI, which 10 includes esophagus, stomach, small 11 intestine, colon, anus, liver, pancreas, 12 bile ducts. 13 Q So if we look at your 14 curriculum vitae, let's take a quick look 15 at that. 16 A Sure. 17 Q We already talked about how 18 it's a different version from the Benicar 19 version. But we'll focus on the 20 Valsartan one. 21 You have that in front of 22 you? I think it was marked as Exhibit 3. 23 MR. SLATER: You're going to 24 question him on the Valsartan case, 25 not the Benicar case?</p>

<p>1 MS. COHEN: Valsartan CC. 2 A I have it. 3 MS. COHEN: So I didn't say 4 that, no. 5 MR. SLATER: So I should go 6 back to the Benicar report? 7 MS. COHEN: If you want to. 8 MR. SLATER: Counsel, I'm 9 asking you. I got confused. Did you 10 say we're on Benicar or Valsartan? 11 MS. COHEN: No. We're on 12 the CV in Exhibit 3, Valsartan. But 13 we may go to the other one too. 14 MR. SLATER: It's your time. 15 It's your use of your time. 16 MS. COHEN: Thank you, Adam. 17 I appreciate that. 18 Q If we look at page 1 of 19 this, this gives your training and 20 education; right, Doctor? 21 A Correct. 22 Q And, again, obviously, it's 23 all focused on pathology; correct? 24 A Well, medical school is not 25 pathology-specific. That was a broad</p>	<p>Page 146</p> <p>1 gastrointestinal, liver and surgical 2 pathology and anatomic pathology. All of 3 these include cancer. 4 Q I'm just asking you the 5 words on there. 6 Is it cancer oncology? 7 A Whether or not the word is 8 there is meaningless. It's included in 9 this. 10 Q You can't look at the page 11 and tell me whether cancer oncology is on 12 there? 13 A The words are not on there. 14 But the training encompassed it. And as 15 I said, I just have to -- it's an 16 important point to me personally. 17 Q And then on page 2 where it 18 talks about organizations, Peer Review, 19 are you on any boards that are specific 20 to cancer? 21 A Boards? 22 Q Yes. 23 A Boards specific to cancer? 24 MR. SLATER: Objection. You 25 can answer.</p>
<p>1 medical education that included rotations 2 in internal medicine, surgery, 3 everything. 4 Q And then it gets into 5 pathology; correct? 6 A Yes. 7 Q And we don't see anything 8 about cancer on page 1, do we? 9 MR. SLATER: Objection. You 10 can answer. 11 A That's a gross 12 mischaracterization. Medical school had 13 quite a bit on cancer. My residency and 14 fellowship training both were heavily 15 focused on cancer. 16 Q Does it say the word 17 "cancer" on page 1? 18 A It doesn't say a word about 19 any specific disease on page 1. 20 Q Does it say anything about 21 oncology on page 1? 22 A What diseases are mentioned 23 on page 1? I don't see any. 24 Q So it included oncology? 25 A Cancer is included in</p>	<p>Page 147</p> <p>1 Q Or an organization. I'm 2 trying to figure out what, if any -- 3 MR. SLATER: Objection. You 4 can answer. 5 Q Members of foreign 6 organizations, Peer Review, any of those 7 specific to cancer on page 2? 8 MR. SLATER: Objection. You 9 can answer. 10 A Okay. Almost any of these 11 will deal with cancer in part. So, you 12 know, papers -- well, other than 13 perhaps -- well, actually, all of them 14 deal with cancer to varying degrees, some 15 quite a lot. And I review papers related 16 to cancer all the time. 17 Q There are organizations that 18 are cancer and oncology; correct? 19 MR. SLATER: Objection. You 20 can answer. 21 A There are ones that are 22 specific to oncology that would not have 23 an interest in inflammatory conditions, 24 yes. 25 Q So there are specific cancer</p>

<p>1 in oncology. We could take out any of 2 our cancer biology experts and people 3 like that or oncology experts. There are 4 specific organizations.</p> <p>5 I'm trying to ask, are you 6 on any specific organizations related to 7 cancer oncology?</p> <p>8 MR. SLATER: Objection. You 9 can answer.</p> <p>10 A Yeah. I mean I'm not in any 11 organization that is exclusive to cancer. 12 I'm in many organizations that deal in 13 large part with cancer.</p> <p>14 Q Sure. I'm asking you a 15 different question, though. And I can 16 certainly pull out our cancer expert's CV 17 if we need to.</p> <p>18 Are you in any of those 19 organizations?</p> <p>20 MR. SLATER: Objection. You 21 haven't listed them.</p> <p>22 A I think I answered that.</p> <p>23 Q So you're not on any of 24 those?</p> <p>25 MR. SLATER: Objection. You</p>	<p>Page 150</p> <p>1 can answer.</p> <p>2 A Well, there would be no 3 reason for me to go to a medical oncology 4 meeting. I don't prescribe any 5 medicines.</p> <p>6 Q How about a surgical 7 oncology meeting? Do you go to any of 8 them?</p> <p>9 A No.</p> <p>10 Q How does it work at 11 Columbia? Just tell me about the way it 12 works. There's a pathology department, 13 and that's where you're housed, if you 14 will: You're a member of that; right?</p> <p>15 A Yes.</p> <p>16 Q There's probably a surgery 17 department as well; correct?</p> <p>18 A There is.</p> <p>19 Q Now, where are the cancer 20 specialists located? Are they in their 21 own group?</p> <p>22 MR. SLATER: Objection. You 23 can answer.</p> <p>24 A So I mean cancer care, 25 monitoring cancer care is really a</p>
<p>1 can answer.</p> <p>2 A I'm in societies and 3 organizations that deal in large part 4 with cancer. College of American 5 Pathologists, for instance, puts out the 6 guidelines for the diagnosis of many 7 types of cancer. And I'm involved with 8 those organizations. But I mean if -- 9 I'm not a member of any societies that 10 deal exclusively with cancer.</p> <p>11 Q Do you ever attend their 12 meetings?</p> <p>13 A College of American 14 Pathologists?</p> <p>15 Q No. The oncology meetings, 16 cancer meetings.</p> <p>17 A The meetings I attend, I 18 frequently attend USCAP and the CAP, 19 well, most often, the CAP. And they deal 20 in large part with cancer. But I have 21 not gone to American Association for 22 Cancer Research.</p> <p>23 Q Or oncology meetings, you 24 don't go to their meetings, I take it?</p> <p>25 MR. SLATER: Objection. You</p>	<p>Page 151</p> <p>1 multidisciplinary endeavor. So you have 2 medical oncologists who -- I'm inferring 3 that you're referring to when you say 4 cancer doctors, or maybe I'm wrong there.</p> <p>5 Q No.</p> <p>6 A You said medical oncologists 7 who are a division of the division of 8 internal medicine at Columbia. You have 9 surgical oncologists who are housed under 10 the department of surgery. You have 11 radiation oncologists who I think are 12 their own department. I don't think 13 they're under radiology, and you have 14 radiologists who specialize in cancer 15 diagnostics.</p> <p>16 Q Under Columbia University, 17 there's the -- on the Web site, there's a 18 whole section on cancer, and there's the 19 cancer center, the cancer center which is 20 designated by The National Cancer 21 Institute. Are you part of that cancer 22 group?</p> <p>23 A I don't know. I work with 24 them all the time. I'm not sure if 25 pathology is included. If pathology is</p>

<p>1 included, I would be part of it. But I 2 don't know if pathology is included. 3 Q Does Columbia University 4 Herbert Irving Conference Cancer Center, 5 HICCC, which again is set up by The 6 National Cancer Institute -- 7 A I did not say that. 8 Q -- recognized as a 9 comprehensive cancer center by The 10 National Cancer Institute? 11 A Okay. I agree. 12 Q Are you part of that, are 13 you listed there? 14 A I don't know. 15 Q Do you participate in any of 16 their meetings of things? 17 A Definitely, yes. 18 Q Would it surprise you if we 19 looked at this and your name didn't come 20 up? 21 MR. SLATER: Objection. You 22 can answer. 23 A I really don't know. I 24 don't know if there are any pathologists 25 listed. If there are, I would expect</p>	<p>Page 154</p> <p>1 can answer. 2 A I'm sure the medical 3 oncologists are listed: Dr. Schwartz, 4 Dr. Manji, Dr. Drake. Yes. I know the 5 medical oncologists. As far as the 6 people who do only research and do not 7 see patients and are cancer researchers, 8 those are not people I would likely 9 interact with closely. I am aware of 10 some of them. 11 Q Do you read their research? 12 A Sometimes. 13 Q Do you know whether they 14 have published or had anything -- doing 15 any research on the issues of 16 nitrosamines, Valsartan, anything related 17 to this case? 18 A To my knowledge, no. 19 Q When Mr. Slater first got 20 you involved in the case and we just 21 looked at those, pull it back up, at the 22 invoices. Let's see. Starting in 23 August, August 12th of 2020, and we 24 talked about sort of the initial question 25 that was framed for you.</p>
<p>1 probably to be one of them. But I don't 2 know. 3 Q And are there at Columbia 4 what's called cancer biologists or cancer 5 researchers who specifically look at 6 issues of causality in cancer? 7 A I presume so. 8 Q Have you ever talked to any 9 of them about the issues in this case? 10 A No. 11 Q Have you ever talked to them 12 about causation issues for any of the 13 patients? 14 A It doesn't sound 15 implausible. But as I sit here today, I 16 don't have a specific recollection. 17 Q And, again, could you name 18 any of the cancer biologists or cancer 19 researchers that are known to be part of 20 this -- where it said the Herbert Irving 21 Comprehensive Cancer Center? Do you know 22 any of the people there who are on the 23 cutting edge on the study of cancer 24 biology? 25 MR. SLATER: Objection. You</p>	<p>Page 155</p> <p>1 And I want to ask, were you 2 asked to assume anything in the case? 3 A Not to my recollection. 4 Q When you said you read over 5 your report, you said maybe a couple of 6 times in recent days? 7 A Yes. 8 Q Did you read it last night? 9 A I did. 10 Q Did you read it this 11 morning? 12 A No. 13 Q How many times did you read 14 it yesterday? 15 A Probably twice. 16 Q And, again, I know I asked 17 you about epidemiology. 18 You're also not a 19 biostatistician; correct? 20 A Right. I understand 21 biostatistics. I have a functional 22 knowledge of it. But I am not a 23 biostatistician by any stretch. 24 Q And I mean probably everyone 25 in this room, we all have a different</p>

<p>1 functional knowledge of things.      2        But I'm asking you      3 specifically, do you hold yourself out as      4 an expert in biostatistics or as a      5 biostatistician?      6        A No, not an expert or a      7 particular biostatistician. I have a      8 working knowledge, functional knowledge      9 of biostatistics. And I do use that      10 knowledge to analyze medical literature      11 as part of my normal practice.      12        Q And you're not a cancer      13 biologist; correct?      14        MR. SLATER: Objection. You      15 could answer.      16        A Again, I have a deep      17 knowledge of cancer biology and cancer --      18 I'm an applied -- I have a deep knowledge      19 of cancer biology, cancer physiology. I      20 am not a researcher devoted entirely to      21 cancer biology.      22        Q No.      23        You've told us today what      24 your cancer experience is; correct?      25        A Certainly not. I haven't</p>	<p>Page 158</p> <p>1 of -- I know you're obviously an      2 associate professor.      3        How many do what you do as      4 part of the anatomic pathology group?      5        MR. SLATER: Objection. You      6 could answer.      7        A There are about 24 anatomic      8 pathologists at Columbia. There are five      9 or six of us in the -- five of us active      10 in the GI and liver subdivision.      11        Q And so anytime there's a GI      12 issue, they tend to come to one of you      13 five?      14        A Yes.      15        Q And the same would be      16 true -- what are the other areas      17 within -- if you're in --      18        A What other sub-specialties?      19        Q Yes.      20        Is breast cancer a special      21 one?      22        A Partially, yes.      23        Q Breast cancer patients would      24 tend to go to those people?      25        A Tend to, yes.</p>
<p>1 told you all of it.      2        Q No.      3        You told me about some of      4 the articles you identified for us;      5 correct?      6        A I did tell you that.      7        Q You told us about how as      8 part of your work as an anatomic      9 pathologist where you sometimes make      10 diagnoses that you incorporate into the      11 report; correct?      12        A Almost every day. I      13 diagnose probably thousands of cancer      14 cases.      15        Q And of the thousands of      16 cancer cases, what percentage are liver      17 or hepatocellular?      18        A A very rough estimate. I      19 would say perhaps 20 percent, 15 to      20 20 percent, mainly because the incidents      21 of liver cancer is much lower than some      22 other common cancers like colon cancer or      23 prostate cancer.      24        Q How many pathologists do      25 what you do at Columbia, that is a part</p>	<p>Page 159</p> <p>1        Q What other areas, if you      2 know?      3        A Neuropathology is a separate      4 area; non-neoplastic kidney is another      5 area; skin, inflammatory conditions of      6 the skin anyway, go to a separate area;      7 hemopathology, blood cancers.      8        Q Different people deal with      9 that; right?      10       A Yeah. I might see them. If      11 I see a case, let's say leukemia or      12 lymphoma, I'd say this is not for me.      13       Q You send those to the      14 subspecialists?      15       A Right.      16       Q How about bladder? Would      17 other people deal with bladder?      18       A No. Bladder and prostate go      19 to the general surgical pathology      20 service. And this is very detailed      21 minutia of how our department is. But      22 those go to general surgical pathology      23 which I rotate on for three months of the      24 year. So diagnosing bladder cancer, I      25 probably do 50 to 100 cases a year;</p>

1 prostate cancer, probably the same; 2 kidney cancer, probably less because just 3 the incident's less; 25 kidney cancers 4 per year. 5 Q How many pathology specimens 6 typically are you looking at? And if you 7 can't tell me because you don't keep 8 track of those, it's fine to estimate. 9 A Roughly speaking, I look at 10 around 6,000 a year. And I'm on service 11 75 percent of the time. So we could do 12 the math. 13 Q And you're saying 14 20 percent -- I may have written this 15 down. 16 What percentage are cancer 17 of the 6,000? 18 A Variable. To be in the 19 ballpark, I would say 10 percent. 20 Q And then of the 10 percent, 21 20 percent are of the liver? 22 A Again, ballpark, that's 23 correct. 24 Q Colorectal are in its own 25 group?	Page 162	Page 164 1 MR. SLATER: Objection. You 2 can answer. 3 A I'm not an expert on the 4 management of hypertension. 5 Q Before this litigation, 6 getting involved in this litigation in 7 the fall of 2020, I take it you didn't do 8 any research on NDMA, NDEA or Valsartan? 9 MR. SLATER: Objection and 10 asked and answered. You can answer. 11 She's only asking if you did the 12 research, not the reason for which 13 you did the research. 14 A Okay. Then the answer is 15 yes. 16 Q Let me ask it this way. 17 Before this litigation, 18 meaning Valsartan, and meeting with Mr. 19 Slater in the fall of 2020, did you ever 20 do any research outside of the litigation 21 on NDMA, NDEA or Valsartan? 22 MR. SLATER: Objection. 23 Counsel, you asked this question 24 before. I mean I'll let him answer 25 again because it's one question. But
1 A It's part of GI which I do 2 several ones a year as well. This again 3 gets into some minutia. If there are too 4 many cases of GI, then things go to 5 surgical pathology. I diagnose a lot of 6 colon cancer a year, probably 100 cases a 7 year, maybe 50, something like that. 8 Q Other than the blood 9 cancers, are there any cancers that you 10 absolutely will not get involved in? 11 MR. SLATER: Objection. 12 Lack of foundation. You could 13 answer. 14 A Primary brain cancers. 15 Q Now, also, before I go back 16 to the point I started with on this path 17 was about assumptions, I do want to ask 18 you, you're not a pharmacologist; 19 correct? 20 A Correct. 21 Q You're not a toxicologist; 22 correct? 23 A Correct. 24 Q You're not an internal 25 medicine hypertensive expert?	Page 163	Page 165 1 you're retreading ground now 2 repeatedly. You can answer. 3 MS. COHEN: And I'll just 4 state I disagree on the record. 5 A No. 6 Q Now, on the issue of 7 assumptions, again, you understand as an 8 expert witness, your job, your role is to 9 give opinions; correct? 10 MR. SLATER: Objection. You 11 can answer. 12 A As long as we're saying that 13 they're scientific or medical opinions to 14 a reasonable degree of medical certainty, 15 then yes. 16 Q And that's what you 17 understand is important as part of your 18 expert report, your report and your 19 testimony; correct? 20 MR. SLATER: Objection. You 21 can answer. 22 A Yeah. I mean I considered 23 my role to look through the medical and 24 scientific literature to form an opinion 25 and then to express that opinion.

<p>1 Q And as you said, with a 2 requisite degree of certainty, with a 3 reasonable degree of medical certainty?</p> <p>4 A Yes.</p> <p>5 Q Your job is not to come in 6 here or in your report and speculate; 7 correct?</p> <p>8 A Yeah, correct.</p> <p>9 Q It would be improper to 10 guess; correct?</p> <p>11 MR. SLATER: Objection. You 12 can answer.</p> <p>13 A And that's a broad 14 hypothetical. But generally speaking, I 15 would try to avoid any guesses.</p> <p>16 Q And you're not -- again, you 17 think it would be improper to assume 18 things that you don't know to be true; 19 correct?</p> <p>20 MR. SLATER: Objection. You 21 can answer.</p> <p>22 A You know, it's such a broad 23 question that it's hard for me to give -- 24 we assume many things throughout the 25 normal course of doing business. So I</p>	<p>Page 166</p> <p>1 report where speculation, or even one 2 might say guesses do sometimes come into 3 reports. If there is a specimen that is 4 not entirely diagnostic, it's not really 5 my job to say I don't know what this is, 6 period. I would go through a standard 7 workup which might include going to 8 certain colleagues, doing additional 9 testing, show it to colleagues, maybe 10 even send it to another institution and 11 to have them take a look and I still 12 don't have an answer and no one I come in 13 contact with has a firm answer, then I 14 would write a differential diagnosis 15 which is, you know, some thoughts on what 16 it could be. It's not based on nothing. 17 It's not wild speculation. It's based on 18 previous cases I've seen or descriptions 19 in the literature or what have you.</p> <p>20 To some extent, it's a 21 homework assignment for whoever sent the 22 specimen because now they need to go and 23 think about, okay, Dr. Lagana suggested 24 Diagnosis X, Y and Z, is there a blood 25 test for this. And I might say I</p>
<p>1 don't think I assume anything beyond -- 2 you know, for example, if I download 3 something from the IARC Web site, I 4 assume that I'm getting what the IARC 5 meant to upload. But for all I know, 6 Russian hackers could have changed it. 7 So I can't say, oh, I've made zero 8 assumptions. Of course, I made normal 9 assumptions like any person would. But I 10 don't think I made any assumptions that 11 are outside of the realm of how I 12 normally go about my business.</p> <p>13 Q What I'm asking is, let's 14 put it in the context of your clinical 15 practice and how you do things.</p> <p>16 When you write one of your 17 reports based on your specimens and 18 review of specimens, you're not going to 19 put in there assumptions about what may 20 or may not be in there; correct?</p> <p>21 MR. SLATER: Objection. You 22 can answer.</p> <p>23 A Well, that's an interesting 24 point. I can't really agree with that. 25 There are times in a surgical pathology</p>	<p>Page 167</p> <p>1 wouldn't do this blood test, I would do 2 this imagining, something like that.</p> <p>3 Q Would you ever say in a 4 report I assume this finding is cancer or 5 would you say in my opinion, it's cancer?</p> <p>6 A If something is diagnostic 7 of cancer, I wouldn't -- I mean I guess 8 it's implied that it's an opinion. But I 9 would just write hepatocellular 10 carcinoma, period; invasive 11 adenocarcinoma, period; sphenoid cell 12 carcinoma, period.</p> <p>13 Q So I'll get back to that in 14 a minute.</p> <p>15 But have you ever had a 16 situation where you've turned down a 17 legal case -- and I know you didn't get 18 many from your signing up of these 19 organizations. But did you ever turn 20 down a legal case and say I'm not the 21 right person for this, it's not my area 22 of expertise?</p> <p>23 A Yes.</p> <p>24 Q And you would do that; 25 right?</p>

<p>1 A Yeah. I have done that.</p> <p>2 Q What type of case have you 3 turned down?</p> <p>4 A Let me think. It's not 5 terribly infrequent that I'll get asked 6 to look at a case that is not really like 7 cytology cases, for example. I don't 8 practice cytopathology. So it's not too 9 infrequent that I'll get asked to look 10 at, say, like a cytology specimen from 11 the pancreas because I do practice 12 pancreatic pathology, but not in the 13 fashion that a cytopathologist would. 14 That would be a common request that I 15 would turn down.</p> <p>16 Q I'm sure you said from time 17 to time, I'm a pathologist, this is far 18 afield and outside my area of expertise; 19 correct?</p> <p>20 MR. SLATER: Objection. You 21 can answer.</p> <p>22 A Usually, when I get asked to 23 look at a case, it is reasonable for a 24 pathologist to look at a case. 25 Occasionally or often, questions will</p>	<p style="text-align: right;">Page 172</p> <p>1 Bradford Hill diagnosis, give a 2 differential diagnosis, apply a 3 methodology, you have to have the 4 grounding and the expertise in that area; 5 correct?</p> <p>6 MR. SLATER: Objection. You 7 could answer.</p> <p>8 A So I'm still not entirely 9 sure I understand.</p> <p>10 Q Do you agree -- we've 11 already looked at the earlier reports, 12 your differential diagnosis in this case, 13 and we talked about Benicar is grounded 14 in your clinical expertise; correct?</p> <p>15 MR. SLATER: Objection. You 16 could answer.</p> <p>17 A Well, in this case, I 18 haven't issued a differential diagnosis. 19 I haven't looked at any specific cases 20 with respect to this. In the Benicar 21 case, sure, then I looked at individual 22 patients. And for those patients, I 23 could put together a differential 24 diagnosis.</p> <p>25 Q Let's put aside the</p>
<p>1 come up in the case where I don't have an 2 opinion. And I have to express. And I 3 don't have an opinion on this.</p> <p>4 Q Did you say that to Mr. 5 Slater about anything? Did you say there 6 are certain areas I can't get into this 7 litigation, I can only cover pathology?</p> <p>8 MR. SLATER: Objection. You 9 can answer.</p> <p>10 A Yeah. I mean there are 11 parts of this litigation that we've 12 discussed that I've tried to familiarize 13 myself with. But I have definitely 14 expressed to Mr. Slater that they would 15 be better covered by a different expert.</p> <p>16 Q For example, if you're 17 giving a differential diagnosis or 18 applying a methodology, you have to 19 understand how the methodology in the 20 differential diagnosis works clinically; 21 correct?</p> <p>22 MR. SLATER: Objection. You 23 could answer.</p> <p>24 A Sorry. Can you rephrase?</p> <p>25 Q In order for you to do a</p>	<p style="text-align: right;">Page 171</p> <p style="text-align: right;">Page 173</p> <p>1 differential diagnosis. Let's talk about 2 methodology.</p> <p>3 A Okay.</p> <p>4 Q Your methodology and your 5 opinions and your report is basically 6 clinical experience; correct?</p> <p>7 MR. SLATER: Objection. You 8 could answer.</p> <p>9 A It depends on how strictly 10 you want to define clinical. In the 11 issuing of a pathology report for a 12 particular specimen, usually, I don't 13 need to go back to the medical and 14 scientific literature to issue that 15 opinion, although there are times when 16 something is very rare where I do have to 17 go to the primary literature in valuing 18 it. So that's on one level.</p> <p>19 On a higher level, being a 20 pathologist, it requires me to be -- and 21 I am -- an expert on pathobiology. And 22 so to acquire that expertise, I do stay 23 abreast of the medical literature and 24 scientific literature. And I do read it 25 as part of my routine practice.</p>

1 Q Do you recall earlier today  
 2 when you told me that the basis of the  
 3 methodology you applied in this case was  
 4 your clinical work?

5 MR. SLATER: Objection. You  
 6 can answer.

7 A I don't recall saying that  
 8 exactly. I certainly said that with  
 9 respect to when we were reading from the  
 10 Benicar methodology because again, that  
 11 was evaluating specific patients.

12 Q You don't remember saying  
 13 that in this case?

14 A Clinical work informs it.

15 Q Do you understand that --  
 16 well, let me ask this.

17 When you do an expert  
 18 witness report like this, do you take it  
 19 seriously?

20 MR. SLATER: Is that a  
 21 serious question?

22 MS. COHEN: Yes, absolutely.

23 MR. SLATER: If he takes  
 24 this seriously?

25 Q Do you take the expert

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1 answer, you wouldn't make assumptions on  
 2 that; you would actually give opinions;  
 3 correct?

4 MR. SLATER: Objection. You  
 5 can answer.

6 A With respect to the key  
 7 issues, I would look at the literature  
 8 and statements from regulatory agencies,  
 9 like WHO, IARC, FDA, as I did and come to  
 10 an opinion, yeah.

11 Q Page 11 of your report,  
 12 let's look at that for a minute.

13 A Okay.

14 Q And obviously, as you say,  
 15 cancer is a multifactorial disease. And  
 16 you list many things that can contribute  
 17 to carcinogenesis; right?

18 A Yes.

19 Q Then you go on to say,  
 20 "Therefore, for any patient who develops  
 21 cancer and is known to have a significant  
 22 exposure to a probable human carcinogen  
 23 (the levels documented above constitute a  
 24 significant exposure in my opinion), it  
 25 should be assumed that the carcinogenic

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1 witness report in this case seriously?

2 A Yes.

3 Q And do you take it as  
 4 seriously as the testimony you're giving?

5 A Yes.

6 Q And everything you say in it  
 7 is true; correct?

8 A To the best of my knowledge,  
 9 yes.

10 Q Let me have you look at page  
 11 11, going back to the assumption part. I  
 12 asked you before whether you assumed  
 13 anything in this case. And I think what  
 14 you said is you may have made some  
 15 assumptions, but you wouldn't assume  
 16 something that goes to the core issue?

17 MR. SLATER: Objection.

18 Lack of foundation.

19 A I said that we can't get  
 20 through life in any endeavor without  
 21 making some assumptions. And I tried to  
 22 make no more assumptions than I would  
 23 normally make to get through life.

24 Q On the key issue that was  
 25 framed for you that was given to you to

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1 exposure at least increased the risk or  
 2 contributed to the subsequent cancer  
 3 unless there is a convincing body of  
 4 evidence to suggest that the carcinogenic  
 5 insult is null with respect to the  
 6 specific cancer in question."

7 Is that your opinion?

8 A Yes.

9 Q And you don't have any cite  
 10 there, do you?

11 A No.

12 Q And, again, what's your  
 13 definition of significant exposure?

14 What's the basis for it?

15 A Well, the significant  
 16 exposure would vary depending on what the  
 17 carcinogen is. But this statement is  
 18 actually not super controversial.

19 Basically, if you're looking at -- is  
 20 cigarette smoking associated with  
 21 whatever cancer, general baseline, it's  
 22 reasonable to suspect that it is.

23 And, in fact, cigarette  
 24 smoking is associated with lots of  
 25 cancers. But then there are some cancers

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<p style="text-align: right;">Page 178</p> <p>1 which are proven through the research not 2 to be affected by cigarette smoking. And 3 so, fine, we accept that. 4 HPV is another great 5 example. HPV can cause cancer in the 6 mouth like we discussed and the anus. 7 Similar cancers arise in the esophagus. 8 And for many years, there was concern, is 9 HPV causing these esophageal cancers. 10 And it had to be disproven that it was 11 not. So now we know it does not. 12 Anyway, I think if you're 13 asking me what level is a significant 14 exposure to NDMA and contaminated 15 Valsartan, is that the question you want 16 me to address? 17 Q No. 18 My question was -- you had 19 no cite. 20 And I'm asking you, what is 21 your definition and the basis for the 22 words "significant exposure"?</p> <p>23 MR. SLATER: Which question 24 is it? Sorry. It seemed like there 25 was a few questions. I object. You</p>	<p style="text-align: right;">Page 180</p> <p>1 Q That's your opinion; 2 correct? 3 A That's my opinion. 4 Q You said I think about the 5 prior sentence, and I want to ask you, 6 you don't think it's very controversial. 7 Do you think this sentence is not 8 controversial either? 9 MR. SLATER: Objection. 10 A Well, with respect to NDMA, 11 you have a compound that is a known 12 mutagen, well-known mutagen as defined by 13 IARC, cohort of concern where it's -- 14 capacity to cause mutation. We know 15 exactly how it does it, by alkylating DNA 16 and causing methylguanine which is one of 17 the main drivers of mutation in cells. 18 So if someone had an 19 exposure to a drug, to a substance, that 20 was causing -- that was a known mutagen, 21 then I think -- and someone then develops 22 a cancer, one would at least have to be 23 very suspicious that the known mutagen, 24 which messed up their DNA, contributed in 25 part or largely to their cancer.</p>
<p style="text-align: right;">Page 179</p> <p>1 can answer. 2 A It depends on what the 3 exposure is. 4 Q So it's not an absolute 5 answer there; it depends on the exposure; 6 right? 7 A What is a significant 8 exposure? Yes, certainly. 9 Q And you gave me two specific 10 answers: Cigarettes and HPV? 11 MR. SLATER: Objection. You 12 can answer. 13 A Yeah. I mean -- right. 14 Radiation is another example. Having a 15 lung chest x-ray is okay; having 1,000 is 16 not. 17 Q You say next, "The crucial 18 point is that we start from the 19 assumption that exposure to a human 20 carcinogen contributed to carcinogenesis 21 in a patient with a cancer unless there's 22 convincing evidence to the contrary." 23 Now, you don't have any cite 24 there; correct? 25 A That's right.</p>	<p style="text-align: right;">Page 181</p> <p>1 Now, it may be that some 2 cancers have nothing to do with this. 3 And the literature could maybe eventually 4 show that. But, you know, there's never 5 been an experiment where we gave humans 6 massive doses of NDMA because it would be 7 wildly unethical. 8 Q So my question was, as this 9 sentence, do you think that this is 10 controversial or not? 11 MR. SLATER: Objection. You 12 can answer. 13 Q What you said there? 14 A Let me read it again. It 15 could be controversial. 16 Q You want to go back to the 17 prior sentence and tell me whether you 18 think the prior one is controversial now 19 that you've had a chance to read it 20 again? 21 MR. SLATER: Objection. You 22 can answer. 23 A It's hard for me to 24 speculate on what other people might read 25 into my words. So maybe I shouldn't have</p>

<p>1 said it's not controversial. I don't 2 know whether it is or is not. I guess 3 you have to ask a lot of different 4 experts, what they think.</p> <p>5 Q And you haven't run those 6 two sentences by any cancer experts, have 7 you?</p> <p>8 A I am a cancer expert. But I 9 haven't asked anyone else to read it.</p> <p>10 Q What I mean by that, any 11 cancer biologist, any epidemiologist, any 12 oncologist? Have you run that by any of 13 them?</p> <p>14 A I haven't run the report by 15 any of them, other than Mr. Slater.</p> <p>16 Q One of the things you say in 17 your report -- and I'm sorry to jump 18 around here -- speaking of controversy, 19 on page 5 --</p> <p>20 MR. SLATER: Where are we 21 now? In the same report?</p> <p>22 MS. COHEN: Yes.</p> <p>23 MR. SLATER: We're on page 24 5?</p> <p>25 MS. COHEN: Yes.</p>	<p style="text-align: right;">Page 182</p> <p>1 of a cancer.</p> <p>2 Q Is it your opinion to a 3 reasonable degree of medical certainty 4 that one of these mutations, one mutation 5 can lead to cancer?</p> <p>6 MR. SLATER: Objection. You 7 can answer.</p> <p>8 A Well, there are a lot of 9 examples of cancers that are caused by 10 one mutation.</p> <p>11 Q So the answer is, yes, you 12 believe one mutation can lead to cancer?</p> <p>13 A Yeah. Not that it always 14 does, not that every cancer only has one 15 mutation. There's a lot of data here 16 that we're drilling down to one very 17 narrow question. But on that very narrow 18 question, can one mutation cause a 19 cancer? Yeah.</p> <p>20 Q And you can't give us any 21 cite to that; you just believe that to be 22 true?</p> <p>23 A Well, CK mutations in the 24 gastrointestinal stromal tumors are a 25 well-known example; the BRAF V600</p>
<p>1 Q There's a sentence here that 2 caught my attention. It says -- bottom 3 paragraph, it says, "If one of these 4 mutations causes the cell to become 5 immortalized, then that can be the start 6 of a cancer."</p> <p>7 There's no citation there; 8 correct?</p> <p>9 A That's the basics of cancer 10 biology. But I didn't cite anything, no.</p> <p>11 Q Do you believe that one 12 mutation can cause a cell to become 13 immortalized and start cancer?</p> <p>14 A Yeah, certainly. It 15 depends -- it doesn't always happen that 16 way. It's not that once a mutation 17 happens, you have to get a cancer. There 18 are various ways in which the body may be 19 able to correct that error, that 20 mutation, if we call it a mutation error. 21 But that is the basis of how tumors 22 begin. The mutation causes a cell to 23 become immortalized. And it starts 24 reproducing, reproducing. If the body 25 fails to stop it, then that is the start</p>	<p style="text-align: right;">Page 183</p> <p>1 mutation in melanoma, in some colorectal 2 cancers. Those are point mutations. And 3 that one mutation certainly is a main 4 driver of the cancer. BRCA1, PROP1 5 mutation, breast ovarian cancers. This 6 is not rare where one mutation drives a 7 cancer.</p> <p>8 Q But have you ever given any 9 talks, not on pathology, talks on cancer 10 and cancer biology, cancer causation, 11 anything like that?</p> <p>12 MR. SLATER: Objection. You 13 can answer.</p> <p>14 A I'm sure talks that I've 15 given have dealt with those issues. I 16 don't know if any of them were 17 specifically and exclusively on those 18 issues.</p> <p>19 Q So you may have been talking 20 about pathology issues, and something 21 related to cancer came up?</p> <p>22 A Yeah. You can't really 23 separate pathology and cancer this way. 24 Cancer is a major concern of pathology. 25 If there was no cancer, you know, we'd</p>

<p style="text-align: right;">Page 186</p> <p>1 have maybe 10 percent of the pathologists 2 that we have.</p> <p>3 Q But etiology of cancer is 4 not part and parcel of what you do every 5 day? We've already discussed that; 6 right?</p> <p>7 MR. SLATER: Objection. You 8 can answer.</p> <p>9 A Well, I want to make sure 10 we're clear on that point. I said I 11 don't include in the etiology in a report 12 for an individual patient in most 13 instances. And that is true. But 14 knowing the etiology of cancers and what 15 causes cancer, what's the pathobiology of 16 cancer from both the population level 17 down to a molecular level is definitely 18 part and parcel of what a pathologist 19 needs to know.</p> <p>20 Q But you don't always know 21 the pathobiology, nor the etiology of 22 cancer when you're writing your reports, 23 do you?</p> <p>24 MR. SLATER: Objection. You 25 can answer.</p>	<p style="text-align: right;">Page 188</p> <p>1 times a year; correct?</p> <p>2 MR. SLATER: Objection. You 3 can answer.</p> <p>4 A I believe I said I examined 5 around 6,000 specimens per year.</p> <p>6 Q I'm sorry.</p> <p>7 And 10 percent of cancer, 8 that's 600?</p> <p>9 A Yeah. I think that that's 10 directionally right.</p> <p>11 Q So about 600 patients a 12 year.</p> <p>13 You can't possibly know the 14 multifactorial issues that you just 15 raised in your own report for those 600 16 patients, can you?</p> <p>17 MR. SLATER: Objection. You 18 can answer.</p> <p>19 A Yeah. I mean again, it 20 depends on -- it depends largely on how 21 wide or narrow you want to make that 22 question. It's really not a question I 23 can answer in that context. There are 24 things I know and things I don't know.</p> <p>25 Q And the factors that you</p>
<p style="text-align: right;">Page 187</p> <p>1 Q You couldn't; right?</p> <p>2 A It depends how high up you 3 want to go with that question. Do I know 4 an etiology for every cancer I diagnose? 5 No. But I'm aware of the molecular 6 mechanisms behind any cancer I would 7 diagnose. So in a narrow level, the 8 answer usually is yes. On a broad level, 9 it's sometimes yes, sometimes no.</p> <p>10 Q Because as you say on page 11 11, we've looked at this before, "Cancer 12 is a multifactorial disease. Permissive 13 genetics, environmental exposures, 14 epigenetics, random chance, bad luck all 15 contribute to carcinogenesis."</p> <p>16 You don't know what's 17 happening with people in all of those 18 areas, do you?</p> <p>19 MR. SLATER: Objection. You 20 can answer.</p> <p>21 A I haven't cited to a lot of 22 those areas. I don't necessarily have a 23 complete picture of all of them.</p> <p>24 Q I want to just quickly -- 25 you said you make cancer diagnosis 6,000</p>	<p style="text-align: right;">Page 189</p> <p>1 listed there are just a small part of the 2 real multifactorial set of issues that 3 can cause cancer; right?</p> <p>4 A I wouldn't say that genetics 5 environment, epigenetics and chance 6 constitute a small part. I would say 7 that probably constitutes a large part.</p> <p>8 Q You mean the broad swaths 9 you describe in there?</p> <p>10 A Yes.</p> <p>11 Q Everybody has bad luck?</p> <p>12 MR. SLATER: Objection. You 13 can answer.</p> <p>14 A Yeah. I mean as I say, 15 cancer is a multifactorial disease. I 16 listed some of the most important factors 17 here, some of which I might know, some of 18 which I don't know when I diagnose a 19 particular patient. But it is important 20 for a pathologist to have a working 21 knowledge of all of these things at a 22 high level at least.</p> <p>23 Q And how do you get the 24 working knowledge? You're not talking to 25 the patient; correct?</p>

<p>1 A Yeah.</p> <p>2 Q So you look at medical</p> <p>3 records?</p> <p>4 MR. SLATER: Objection. You</p> <p>5 can answer.</p> <p>6 A Well, I mean I look at the</p> <p>7 patient medical records and the medical</p> <p>8 and scientific literature.</p> <p>9 Q But in terms of, you said</p> <p>10 here, it's important for a pathologist to</p> <p>11 have a working knowledge of these things</p> <p>12 at a high level.</p> <p>13 And I'm asking, in your</p> <p>14 given 600 patients per year of cancer,</p> <p>15 20 percent of which are of the liver, the</p> <p>16 ones that we've talked about, again,</p> <p>17 working knowledge would come from either</p> <p>18 discussion with the referring doctor,</p> <p>19 doctors treating the patient, Number One;</p> <p>20 Number Two, the medical records; right?</p> <p>21 MR. SLATER: Objection. You</p> <p>22 could answer.</p> <p>23 A That's not always the case;</p> <p>24 you know, for liver cancers, I might look</p> <p>25 at the benign liver next to the tumor and</p>	<p>Page 190</p> <p>1 1:01 p.m. Eastern Time.</p> <p>2 (A lunch recess was taken.)</p> <p>3 THE VIDEOGRAPHER: We are</p> <p>4 now back on the record. The time is</p> <p>5 1:43 p.m. Eastern Time.</p> <p>6 Q Thank you, Doctor. Welcome</p> <p>7 back after lunch.</p> <p>8 A Thank you.</p> <p>9 Q We'll just pick up. Just a</p> <p>10 couple of questions still lingering from</p> <p>11 before that I want to go back to before</p> <p>12 we go forward. And that's on page 11 of</p> <p>13 your report. I don't know that I ever</p> <p>14 got an answer from you about what your</p> <p>15 definition of significant exposure is.</p> <p>16 Can you tell us?</p> <p>17 A Sure. Are you asking in a</p> <p>18 general sense or as it relates to NDMA?</p> <p>19 Q Well, you said, "Therefore,</p> <p>20 for any patient who develops cancer, and</p> <p>21 is known to have a significant exposure</p> <p>22 to a probable human carcinogen."</p> <p>23 I'm talking about in that</p> <p>24 sentence, what are you referring to?</p> <p>25 A Well, significant would</p>
<p>1 see features of alcohol, cirrhosis, for</p> <p>2 example. So then I can get the</p> <p>3 information I need right off the slide.</p> <p>4 Other times I might talk to the</p> <p>5 submitting physician. I might read the</p> <p>6 patient's chart. I might go to the</p> <p>7 medical and scientific literature. Any</p> <p>8 of those things would be not out of the</p> <p>9 standard way to do things.</p> <p>10 Q But from your perspective,</p> <p>11 just so we're clear before we move off of</p> <p>12 this, in terms of the factors, the ones</p> <p>13 you list here -- permissive generics,</p> <p>14 environmental exposures, epigenetics and</p> <p>15 random chance -- are the top ones for</p> <p>16 you? Those are the top factors; correct?</p> <p>17 MR. SLATER: Objection. You</p> <p>18 can answer.</p> <p>19 Q That's why you put them in</p> <p>20 your report?</p> <p>21 A Yeah. I think those are</p> <p>22 probably the most powerful predictors of</p> <p>23 cancer development.</p> <p>24 THE VIDEOGRAPHER: We're now</p> <p>25 off the record. The time is</p>	<p>Page 191</p> <p>1 depend on the carcinogen.</p> <p>2 Q So you don't have any</p> <p>3 parameters; you're just saying whatever</p> <p>4 it is in a given situation?</p> <p>5 MR. SLATER: Objection. You</p> <p>6 can answer.</p> <p>7 A Well, I have plenty of</p> <p>8 parameters. But the parameters would be</p> <p>9 different if we're talking about --</p> <p>10 depending on the carcinogen in question.</p> <p>11 If you want to go to NDMA specifically,</p> <p>12 the dietary literature seems to show a</p> <p>13 fact that around 100 nanograms per day,</p> <p>14 the FDA has set their maximum allowable</p> <p>15 amount at 96 nanograms per day. So I</p> <p>16 mean anything above the FDA's maximum</p> <p>17 allowable would strike me as significant</p> <p>18 exposure.</p> <p>19 Q What do you have as the</p> <p>20 FDA's maximum allowable?</p> <p>21 A 96 nanograms per day in a</p> <p>22 pill.</p> <p>23 Q So basically, the purpose of</p> <p>24 this page of your report, when you use</p> <p>25 the words "significant exposure" related</p>

<p>1 to NDMA, you're talking about anything 2 over 96 nanograms? 3 A To the extent that this 4 sentence wasn't specifically about NDMA. 5 And as I said, the specifics of what is 6 significant would depend on the 7 situation. I mean as far as NDMA, even 8 the FDA maximum allowable is an interim 9 maximum allowable. We can live with that 10 for now. The goal is to get to zero 11 because it's a carcinogen. And there is 12 no known safe intake amount. But 13 certainly, 96 nanograms or above is 14 significant. Less may be significant as 15 well.</p> <p>16 Q But for the purpose of this 17 when you use significant, I think you 18 already gave the answer, you're using the 19 96 nanograms by the FDA, and anything 20 above that would be significant?</p> <p>21 MR. SLATER: Objection. You 22 can answer again.</p> <p>23 Q Would you say that?</p> <p>24 A Anything above that is 25 definitely significant. I'm not ruling</p>	<p>Page 194</p> <p>1 etiology of a cancer by looking at the 2 slide. There are many instances in which 3 you can, not all instances, but it's not 4 a blanket statement that I would make, 5 one way or the other.</p> <p>6 The aforementioned 7 HPV-related cancers, I can usually tell 8 just by looking at the slide, whether 9 they are or are not. Liver cancers, I 10 can almost always tell what the cause of 11 the liver cancer was by looking at the 12 slide; you know, lung cancers, you might 13 find an emphysematous lung in which case 14 it would indicate cigarette smoking. So 15 there are many times in which -- 16 including common situations which you can 17 certainly diagnose the cause or know the 18 etiology of the cancer.</p> <p>19 Q There are certain instances 20 where you can, but there are many 21 instances where you cannot; correct?</p> <p>22 A Yeah. There are both 23 instances where you can and instances 24 where you can't.</p> <p>25 Q If you talk about</p>
<p>1 out the possibility that less is 2 significant.</p> <p>3 Q But sitting here today, 4 you're using 96 as significant?</p> <p>5 MR. SLATER: Objection. You 6 could answer.</p> <p>7 A I think it's a reasonable 8 shorthand for the time being.</p> <p>9 Q One other question about 10 something from earlier.</p> <p>11 I think you'll agree with us 12 that in terms of the etiology of cancer, 13 you can't diagnose or know that from 14 looking at a slide or specimen; true?</p> <p>15 MR. SLATER: Objection. You 16 can answer.</p> <p>17 A No. I said I wouldn't agree 18 with that.</p> <p>19 Q Do you think you can tell 20 the sources and using the multifactorial 21 from looking at the specimen?</p> <p>22 MR. SLATER: Objection. You 23 can answer.</p> <p>24 A Well, you said it as a rule 25 that you can't identify the source of the</p>	<p>Page 195</p> <p>1 environmental exposures, genetics, random 2 choice, you wouldn't be able to discern 3 those using your list from looking at a 4 slide?</p> <p>5 MR. SLATER: Objection.</p> <p>6 A Well, as I just mentioned, a 7 lot of the environmental exposures can be 8 figured out by looking at the slides. So 9 that one, yes. Whether -- the person's 10 genetics, there are certainly some tumors 11 that are related to genetic syndromes and 12 have a specific histologic phenotype 13 which I can diagnose. Epigenetic 14 changes, there are certain types of colon 15 cancer, for example, that are thought to 16 be caused by epigenetic phenomenon which 17 do have a characteristic histologic 18 appearance which I could recognize. So I 19 would just avoid blanket statements in 20 that regard because there are different 21 scenarios.</p> <p>22 Q What about let's say, No. 4, 23 random chance, bad luck? You can't piece 24 that together to discern from looking at 25 a slide, can you?</p>

<p style="text-align: right;">Page 198</p> <p>1        MR. SLATER: Objection. You 2    can answer. 3        A    I can't tell you how many 4    times I've looked at this slide and 5    thought, this poor person, that's really 6    an awful lot. 7        Q    Right. 8        But what I'm asking you 9    about -- 10      A    At least in that scenario. 11      Q    And I think what I 12    understood you just said is that there 13    are some instances where there's a 14    specific marker, if you will, a specific 15    pattern on the slide, and there, you can 16    tell an etiology; right? 17      A    Yeah. 18      Q    There are many instances 19    where you just cannot tell looking at a 20    slide, you have to piece together the 21    clinical, pathological points that we 22    made earlier, consulting with another 23    doctor, looking at the medical history; 24    right? 25      A    Both of those are scenarios,</p>	<p style="text-align: right;">Page 200</p> <p>1    different article there. 2        Q    Right. Understood. It was 3    in the wrong place. 4        But you still stand by that 5    original 36 as being an important 6    article; correct? 7        A    Let me see what it is. I 8    remember the author because of the 9    citation. But let me see what the 10    article is. Yeah. I mean this is one of 11    many articles that I considered, was of 12    some importance. 13        I mean really, there are -- 14    I'm not so sure that there's one article 15    that blows any of the others away. It's 16    a weight of evidence approach where I 17    looked at all the relevant literature. 18    And they all contributed, one way or the 19    other, to my understanding of the issue. 20      Q    How many of the articles 21    that you relied on were dietary ones as 22    you described it? 23      A    Pretty good number. If you 24    want to know an exact number, we can go 25    through them.</p>
<p style="text-align: right;">Page 199</p> <p>1    yeah. 2        Q    Now, obviously, your report, 3    which was signed off on July 6th, we're 4    going to accept that as July 26th, you 5    still stand by everything in it; correct? 6        A    Yes, other than the 7    reference issue that we -- the citation 8    issue that we addressed. 9        Q    What you said about that is 10    you wanted to add a cite, not remove a 11    cite? 12        MR. SLATER: Objection. 13      A    Well, the citation that 14    is -- I cited to the wrong Jakszyn paper 15    in that -- I think it's No. 36. And I 16    meant to cite to the one that we 17    provided. 18      Q    You're not backing off of 19    the original 36, are you? 20      A    Well, the original 36, I 21    think I used for a different context. 22    And so in whatever other context I used 23    it, I still stand by that, that usage. 24    It's just where I used it on whatever 25    page that was, I meant to cite a</p>	<p style="text-align: right;">Page 201</p> <p>1        Q    It's okay. 2        A    A decent proportion. 3        Q    I was going to say, would 4    you agree that the vast majority of the 5    articles you cite to are dietary ones 6    that you talked about before? 7        MR. SLATER: Objection. You 8    can answer. 9        A    Vast majority, I think, 10    might be a little bit of an 11    overstatement. I think dietary studies 12    certainly provide a good -- a good 13    portion, some significant portion of the 14    basis of my opinions. But those aren't 15    the only evidence. 16        I mean we also have 17    industrial exposure evidence. We have 18    what is -- we have what could be 19    considered almost an ecological type 20    study where they were looking at the 21    urine of patients in China with cancers 22    of the esophagus. Then we have 23    experimental models in animals. And we 24    have statements from regulatory agencies. 25        Finally, we have some, at</p>

1 least preliminary data in humans related 2 to drugs and I think the Al-Kindi 3 article, for example, where they were 4 looking at the incidents of neoplasms in 5 Valsartan patients before and after the 6 FDA recall. I think that's a really 7 important article. 8 Q We're going to go through 9 all those. 10 Sorry. You're still 11 answering? 12 A Yes. The main gist of that 13 article was, it's very interesting to me 14 because the relative risk of reporting 15 neoplasms associated with Valsartan is, 16 went from 1.7 pre-announcement to like 17 7-point-something post-announcement. So 18 the author said, oh, my God, these people 19 panicked. And they started reporting 20 neoplastic adverse events because of news 21 media or whatever. But it's very 22 striking to me that there is a 1.7 23 relative risk before the announcements 24 were made. So that meant the patients 25 who were using Valsartan were 70 percent	Page 202	1 deal predominantly with background 2 information. 3 Q Page 3 talked about again 4 the methodology that you're going to 5 apply in this case, as we already talked 6 about, about six lines down. Then we get 7 to the background section next, starting 8 at the bottom -- halfway about page 3. 9 And the first sentence 10 is, "NDMA and NDEA are volatile organic 11 compounds known as nitrosamines, found in 12 certain foods, cigarette smoke, water, 13 and other sources as is germane to this 14 discussion, certain medications." 15 And then you cite to 16 References 2, 3 and 4; right? 17 MR. SLATER: Objection. 18 Lack of foundation. Inaccurately 19 read. You can answer. 20 Q I'm sorry. Do you not have 21 foundation for this? Do you feel not 22 qualified -- 23 MR. SLATER: My objection 24 was to you not reading the report 25 accurately, asking to confirm the
1 more likely to report a neoplastic 2 adverse event compared to other ARB 3 users. So I think that's a really scary 4 number. And I mean as a doctor, it 5 scares me. 6 MS. COHEN: Move to strike 7 the part that's not responsive. 8 Q Let's look at in your 9 report, page 3, if you will. So if we 10 look at your report and take it in 11 pieces, if you will. 12 A Sure. 13 Q It's 33 pages. 14 The first, we start with the 15 introduction and the key question which 16 we talked about earlier. 17 And then this background 18 that covers part of page -- well, it 19 covers page 2. 20 A Okay. 21 Q Tell me if you agree with me 22 on that. 23 MR. SLATER: Objection. You 24 can answer. 25 A I agree that page 2 seems to	Page 203	1 report was accurately read. 2 Q Do you feel qualified to 3 speak to this sentence? 4 A The sentence as you read it, 5 yes. 6 Q You can read it right there? 7 A Yes. 8 Q If I skip the parens? 9 A Yeah. 10 Q Certainly, you can look at 11 that. 12 MR. SLATER: Objection. 13 Lack of foundation. 14 Q And if we look at page 34, 15 which is where the citations are, and 16 Cite 2 is the article by Sörgel. I 17 assume you read that one? 18 A Yes. 19 Q And you read all the 20 articles that are cited herein? 21 A I did. 22 Q Let's get that one pulled 23 out, if we can. Just for reference 24 purposes, just so we're all on the same 25 page, some of these articles, you cite to

<p>1 in multiple places; is that correct? If 2 you look at page 7, just so you know 3 where we're going on this, page 3. Then 4 we also cite to the same article on page 5 7. I want to make sure we're all 6 tracking this.</p> <p>7 MR. SLATER: What article 8 are you talking about?</p> <p>9 MS. COHEN: I'm going to 10 hand it to you. This is the Sörgel 11 article which we're going to mark as 12 9.</p> <p>13 (The above-referred-to 14 document was marked as Exhibit 9 for 15 identification, as of this date.)</p> <p>16 MS. COHEN: I'll give a copy 17 to the doctor. Do you need this one, 18 Clem?</p> <p>19 MR. TRISCHLER: If you have 20 it, great. If not, don't worry about 21 it, Lori.</p> <p>22 Q So first of all, on page 3, 23 where we started, you're citing to 24 this -- for the proposition that NDMA, 25 NDEA are volatile organic compounds found</p>	<p>Page 206</p> <p>1 manufacturers. They found between 3,700 2 ng per pill to 22,000 ng per pill in 3 pills using the API produced by ZHP."</p> <p>4 And your sentence is, "This 5 paper equated a pill of Valsartan as 6 being similar to smoking a package of 7 cigarettes as far as cancer-free from 8 NDMA."</p> <p>9 Did I read that correctly?</p> <p>10 MR. SLATER: Objection.</p> <p>11 Lack of foundation.</p> <p>12 A "Cancer risk NDMA."</p> <p>13 Q Let me try it again.</p> <p>14 Package of cigarettes as far 15 as cancer risk from NDMA, and you cite to 16 this; right?</p> <p>17 A Yes.</p> <p>18 Q First of all, you're not an 19 FDA regulatory expert; correct?</p> <p>20 A Correct.</p> <p>21 Q And you -- I take it, you 22 are not an expert on the German Central 23 Pharmacy which is the FDA equivalent; 24 correct?</p> <p>25 A This is what I understood it</p>
<p>1 in various sources; correct?</p> <p>2 MR. SLATER: Objection. You 3 can answer.</p> <p>4 A Yeah. I think I probably 5 used this reference to relate to the part 6 that it was found in Valsartan.</p> <p>7 Q But, again, the sentence 8 here doesn't distinguish between 2, 3, 9 and 4; it basically says, the sentence I 10 read, and you cite to this article?</p> <p>11 MR. SLATER: Objection for 12 multiple reasons, including 13 argumentative. You can answer.</p> <p>14 A The sentence makes various 15 claims. And they are backed by the 16 References 2, 3, 4 of which this is one.</p> <p>17 Q So this is Article 2, and 18 it's listed there -- right there after 19 the first sentence. Then on page 7, if 20 you look over that one where you cite to 21 it again. And here, it says-- I'm going 22 to start at the beginning of that one.</p> <p>23 "The German central pharmacy 24 (German's FDA equivalent) collected 25 Valsartan pills from various</p>	<p>Page 207</p> <p>1 to be.</p> <p>2 Q I'm just --</p> <p>3 A I studied the 4 organization -- I haven't studied the 5 organization in particular detail.</p> <p>6 Q Have you even heard it 7 before this litigation case?</p> <p>8 A The German Central Pharmacy?</p> <p>9 Q Yes.</p> <p>10 A Not that I recall.</p> <p>11 Q This is obviously something 12 new to you.</p> <p>13 But am I correct that you're 14 citing this sentence about a pill of 15 Valsartan as being equivalent to smoking 16 a package of cigarettes?</p> <p>17 MR. SLATER: Objection. You 18 can answer.</p> <p>19 A Could you repeat the 20 question?</p> <p>21 Q So you see No. 2, that's a 22 reference right at the end of that 23 paragraph?</p> <p>24 A Yes.</p> <p>25 Q The sentence that you cite,</p>

<p>1 reference to that is this paper equated a 2 pill of Valsartan as being similar to 3 smoking a package of cigarettes as far as 4 cancer risk from NDMA. That's what you 5 said in this article; right?</p> <p>6 A Yes. That's what I said.</p> <p>7 Q Can you show me where in 8 this article it says that?</p> <p>9 A Okay. It's going to take me 10 some time to find, but sure.</p> <p>11 Q Before you embark on that, 12 let me ask this question.</p> <p>13 Did you re-review all the 14 articles you cited from your report to 15 get ready for today or did you just again 16 not re-review them all, stand by the 17 articles that you had cited?</p> <p>18 MR. SLATER: Objection. You 19 can answer.</p> <p>20 A I certainly re-reviewed a 21 number of them. I don't think I 22 re-reviewed every single one.</p> <p>23 Q Did you re-review this one?</p> <p>24 A Not to my recollection.</p> <p>25 Q So if you can look at this,</p>	<p style="text-align: right;">Page 210</p> <p>1 A I'd have to look some more 2 to see if that's in there or not 3 specifically.</p> <p>4 Q Look at page 404 under the 5 conclusion. And, again, I could have 6 missed that. I will state that on the 7 record. I'm sure Mr. Slater will agree I 8 missed things before. But this to me is 9 the only reference to the cigarettes on 10 page 404 under 5, talking about a 11 reference to a paper reducing nicotine in 12 cigarettes.</p> <p>13 A Well, two possibilities. 14 One is that I forgot the reference or 15 messed up the reference there or that I 16 just extrapolated the fact that they 17 showed 20-some-odd thousand nanograms of 18 NDMA which is a massive amount per pill 19 with the fact that it's -- that's about 20 what's in the package of cigarettes. So 21 it's possible that I wrote that badly. 22 I'm not totally sure. Or maybe it's in 23 here. And we just haven't found it yet.</p> <p>24 Q You would agree a statement 25 like that, which is pretty salacious, if</p>
<p>1 tell me where you got that statement.</p> <p>2 A Sure. Okay. Well, the 3 first relevant portion I see here is in 4 Table 5, the 53.8 parts per million -- 5 not Table 4. It's on Table 5, I guess. 6 But let's look at page 399, Section 3.4, 7 Tablets Tested. 53.8 parts per million 8 and highest dose, which is 320 mg, around 9 20-some-odd thousand nanograms per pill. 10 Package of cigarettes has about 17 to 11 22,000 nanograms of NDMA. So it's in 12 that range.</p> <p>13 Q The article itself doesn't 14 make that statement, though, does it?</p> <p>15 A Equate to the cigarettes?</p> <p>16 Q Yes.</p> <p>17 A I don't see it now. It may 18 be in here. I don't see it there now but 19 does give that amount of NDMA.</p> <p>20 Q Right.</p> <p>21 But in terms of the 22 statement that this paper equated a pill 23 of Valsartan similar to smoking a pack of 24 cigarettes as far as cancerous, those 25 words are not in this article, are they?</p>	<p style="text-align: right;">Page 211</p> <p>1 you will -- let me strike that because 2 I'm getting a laugh across the table.</p> <p>3 MR. SLATER: I didn't laugh, 4 counsel. For the record, I did not 5 laugh.</p> <p>6 Q A pretty serious accusation 7 that a pill is the same as smoking a 8 package of cigarettes, I mean you want to 9 be careful about statements like that in 10 official reports; correct?</p> <p>11 MR. SLATER: Objection. You 12 could answer.</p> <p>13 A Sure, sure. And the crucial 14 point is this paper did show up to 15 22,000 nanograms per pill. And that is 16 about the equivalent of what you find in 17 a package of cigarettes. So I mean it's 18 not -- it may be that I could have 19 written that sentence better. There's a 20 lot of sentences there. And possibly, I 21 could have been -- possibly, it's in 22 here, or possibly, I could have written 23 it better. But the main point is, this 24 is a massive amount of a carcinogen found 25 in these pills.</p>

<p>1 Q Right. 2 But the German Central 3 Pharmacy, the German's FDA equivalent, 4 unless you find it, and I'm getting you a 5 chance to do that later, never said that 6 a pill of Valsartan was equivalent to 7 smoking a pack of cigarettes as far as we 8 know?</p> <p>9 MR. SLATER: Objection. 10 A They said it had up to 11 22,000 nanograms per pill which is 12 equivalent to a package of cigarettes. 13 Whether they made that specific, I 14 thought they did. It's possible I made 15 an error or wrote unclearly. But they 16 did establish a level of NDMA in these 17 pills which is equivalent to a package of 18 cigarettes.</p> <p>19 Q Right. But let me just get 20 this straight so I understand what we 21 could take from your report.</p> <p>22 When you have a reference 23 after a sentence and you say this paper, 24 you're suggesting that the paper covers 25 that point; right?</p>	<p>Page 214</p> <p>1 yesterday. 2 Q The paper, just misciting 3 the paper. But in terms of having a 4 statement like this as attributed to a 5 regulatory agency that isn't in the 6 paper, you're not aware of any other 7 off-the-cuff error; right?</p> <p>8 MR. SLATER: Objection. You 9 can answer the question.</p> <p>10 A I am unaware of any other 11 errors.</p> <p>12 Q If you come across any, will 13 you tell me?</p> <p>14 A Sure.</p> <p>15 Q I know you said at Columbia 16 since you became associate professor, 17 there was like a change in the curriculum 18 vitae and the parameters of that, 19 requirements. Do you remember that?</p> <p>20 A I do.</p> <p>21 Q Are there any parameters at 22 Columbia about papers you write, papers 23 you author, citations? Do they have any 24 like specific rigor required for some of 25 those things?</p>
<p>1 A Yes. 2 Q And you're suggesting that 3 what you put down in the official expert 4 report is in here, in the paper; correct? 5 MR. SLATER: Objection. You 6 can answer. 7 Q That's what you're 8 suggesting about that reference; correct? 9 A Yeah. As I said, it's 10 possible I made a mistake with the 11 reference, or I wrote the sentence a 12 little bit sloppily. It's possible. But 13 the central point there, that, you know, 14 this group found a massive amount of NDMA 15 in Valsartan, an amount of which is 16 equivalent to a package of cigarettes. 17 Q Now, do you know what other 18 errors or mistakes in terms of references 19 are in the report? Have you spotted any 20 other ones since you gone back and read 21 it a couple of more times? 22 MR. SLATER: Objection for 23 multiple reasons including foundation 24 and argumentative. 25 A Sure. The one we discussed</p>	<p>Page 215</p> <p>1 MR. SLATER: Objection. 2 Q Is there any board -- 3 obviously, plagiarism would be a bad 4 thing. 5 Is there any board that 6 reviews papers that professors at 7 Columbia write? 8 MR. SLATER: Objection. You 9 could answer. 10 A Not to my knowledge. 11 Q There's no panel that has to 12 review them since they're going out under 13 your name which is under the auspices of 14 Columbia? 15 MR. SLATER: Objection. You 16 can answer. 17 A They're Peer Reviewed by the 18 journals. 19 Q But the university 20 doesn't -- the institution doesn't weigh 21 in on that? 22 MR. SLATER: Objection. 23 Asked and answered multiple times. 24 You can answer again. It's counsel's 25 time. If she wants to ask the same</p>

<p>1 question over and over, she can.      2 A No.      3 Q You have another citation on      4 page 3 of your report. And I'll make      5 sure I have the right one. You cite to      6 an article, I found the reference, I      7 think it's 31. Which one is this one?      8 Oh. 3. Reference 3 and page 3. Okay.      9 So this is the agency EM.      10 A Okay.      11 Q Referral under Article 31 of      12 directive -- you see the numbers there.      13 This is another one that you cite to.      14 A Okay.      15 Q Do you understand this was      16 written in 2019 after the recall of      17 Valsartan?      18 A Yes.      19 Q And you're citing it in the      20 same place for that same reference about      21 NDMA and NDEA being volatile organic      22 compounds on various other sources. It's      23 in the same spot.      24 MS. COHEN: I'll make this      25 No. 10.</p>	<p>Page 218</p> <p>1 of NDMA, yes.      2 Q And let's turn to page 16 of      3 this paper. We'll go to the paragraph      4 that starts with -- and, again, did you      5 read everything in these articles that      6 you cited to?      7 A I read -- depends on the      8 article. I couldn't say I read every      9 word of every article I read.      10 Q It's not going to be a      11 memory test. I promise.      12 A I read the substance of      13 every article. And some of them in      14 tremendous detail; some of them were a      15 little bit less detailed.      16 Q Was this one that you were      17 focused on?      18 A I read this one with some      19 good attention to detail, yeah.      20 Q Because it was an agency?      21 MR. SLATER: Objection.      22 Q Do you tend to give those      23 more weight?      24 MR. SLATER: Objection. You      25 can answer.</p>
<p>1 (The above-referred-to      2 document was marked as Exhibit 10 for      3 identification, as of this date.)      4 Q This is the European      5 Medicines Agency.      6 What do you know about this      7 group?      8 A This group, to my      9 understanding, is like an EU, an EU FDA      10 equivalent.      11 Q And have you -- did you know      12 anything about this group before this      13 litigation, getting involved as an expert      14 here?      15 A I may have heard of them. I      16 wouldn't say I'm deeply familiar with      17 them.      18 Q So let's look at this one.      19 I think you said this      20 earlier, that NDMA can be created within      21 the body; correct?      22 A Yes.      23 Q Which means it's an      24 endogenous source of NDMA; correct?      25 A There is endogenous creation</p>	<p>Page 219</p> <p>1 A Well, I looked at      2 everything. I put everything together,      3 the studies, the agencies, everything.      4 This one is quite germane to the topic.      5 I did read it in detail.      6 Q So on page 16, it says, "As      7 happening in a real life context, intake      8 of NDMA and NDEA --      9 MR. SLATER: I'm sorry.      10 Where are you? I'm just trying to      11 find where you're reading.      12 MS. COHEN: Page 16.      13 MR. SLATER: I know the      14 page. I don't know where you're      15 reading.      16 MS. COHEN: Second full      17 paragraph, starting at the first of      18 that.      19 Q "As happening in real life      20 context, intake of NDMA and NDEA should      21 be seen in relation to the overall intake      22 of carcinogens, e.g., as benozo[a]pyrene      23 and other PAHs -- I'm probably saying      24 that wrong -- and also other nitrosamines      25 that are present in common food sources</p>

<p style="text-align: right;">Page 222</p> <p>1 such as grilled meat. Exogenous intake 2 of NDMA and NDEA is however considered to 3 be lower than intake of some other 4 carcinogens."</p> <p>5 Did I capture that right?</p> <p>6 A You read it correctly.</p> <p>7 Q And then it says, "The 8 amount of NDMA and NDEA coming from 9 endogenous sources through conversion of 10 amines to NDMA and NDEA in gastric and 11 other acid tissue environments is 12 described to be higher than general 13 exogenous exposure."</p> <p>14 Let me tell you what my 15 interpretation of that is. You tell me 16 if I'm wrong or right.</p> <p>17 That means the body is 18 producing a significant amount of NDMA on 19 its own; right?</p> <p>20 A So it's a very interesting 21 and somewhat controversial area. The 22 first thing to establish there is that 23 any study that has looked at endogenous 24 production of NDMA is doing it by 25 modeling and by inference. There's not</p>	<p style="text-align: right;">Page 224</p> <p>1 of the stomach. It's hard to point to a 2 baseline of endogenous NDMA production.</p> <p>3 Q You agree with this paper 4 that you cite to and rely upon in your 5 report that, again, the body's producing 6 a significant amount of NDMA -- 7 correct? -- endogenously?</p> <p>8 A Yes.</p> <p>9 Q You did not sort of factor 10 that into your analysis of looking at the 11 big question that started off your 12 report? You didn't try to do any 13 determination as to what impact that had; 14 correct?</p> <p>15 MR. SLATER: Objection. You 16 can answer the question.</p> <p>17 Q Did you come up with any 18 measurements?</p> <p>19 MR. SLATER: Objection. So 20 which question is it?</p> <p>21 A I'm sorry. I was thinking 22 about the first question.</p> <p>23 Q It was a recap of that one.</p> <p>24 MR. SLATER: Objection.</p> <p>25 Lack of foundation.</p>
<p style="text-align: right;">Page 223</p> <p>1 really any way to study, to measure that. 2 You'd have to, I don't know, vaporize a 3 human and perform a chromatography on 4 them. So there's no measurement. It's 5 all by inference. And there are some 6 studies, I think some of the ones that 7 are referred to here, are also referred 8 to by Hruday, et al. that do point to 9 very high levels of endogenous and NDMA 10 production.</p> <p>11 On the other hand, there are 12 some like Choi, which I believe I've 13 referenced in my report, which show a 14 much less, a much lower level of 15 endogenous production. So I don't think 16 that we really know precisely how much 17 NDMA is made within the body 18 endogenously.</p> <p>19 And the other thing is that 20 it's highly dependent on a lot of other 21 factors, such as what are you eating, 22 like why are nitrites carcinogenic. 23 Nitrites are considered carcinogenic 24 because they're converted to NDMA when 25 eating proteins in the acidic environment</p>	<p style="text-align: right;">Page 225</p> <p>1 Q If you're not comfortable 2 answering this, let me know.</p> <p>3 MR. SLATER: Objection. I'm 4 asking counsel, what is this? We 5 don't know which question you're 6 referring to.</p> <p>7 Q Are you uncomfortable 8 answering this? If you're not capable of 9 this answering this, just let me know.</p> <p>10 MR. SLATER: Objection.</p> <p>11 Argumentative. Harassing.</p> <p>12 A Okay. So the question is, 13 did I consider endogenous NDMA?</p> <p>14 Q Yes.</p> <p>15 A I certainly did.</p> <p>16 Q Did you come up with any 17 measurements, was my next question?</p> <p>18 A A measurement of endogenous 19 NDMA formation?</p> <p>20 Q Yes.</p> <p>21 A Yes. As I said, I saw 22 numerous sources. They ranged widely on 23 how much there is. So, you know, when 24 you look at dietary studies, presumably, 25 those people are all making endogenous</p>

<p style="text-align: right;">Page 226</p> <p>1 NDMA. So if the studies still show a 2 signal, that the exogenous NDMA is potent 3 with respect to cancer, which many of 4 them, though not all, many of them do, 5 then you would assume that the correction 6 for endogenous NDMA had been made, 7 particularly since some of them 8 explicitly studied nitrite consumption, 9 protein consumption, et cetera.</p> <p>10 Q And on page 3, again, 11 further down in the next sentence, you 12 say, "NDMA can also be created within the 13 body," kind of making that same point 14 that's in the article; right?</p> <p>15 A Yes.</p> <p>16 Q And you're talking about 17 what circumstances after ingestion of 18 nitrates and nitrates plus proteins are 19 the point that we're making here; 20 correct?</p> <p>21 A Nitrites.</p> <p>22 Q Do you know how to correlate 23 or compare the level of NDMA in a 24 Valsartan tablet versus the amount that's 25 being made endogenously?</p>	<p style="text-align: right;">Page 228</p> <p>1 studies that say endogenous production is 2 less than 96 nanograms per day. But 3 those numbers do vary quite a bit as to 4 how much the endogenous production is. 5 And, you know, NDMA is 6 carcinogenic and probably on a dose 7 response curve. So more of it is bad. 8 So if I already have X amount that I'm 9 making and then I start taking Y amount, 10 Y has hurt me.</p> <p>11 Q You have no reason to 12 believe that the NDMA, which is produced 13 endogenously, is any different or less 14 toxic than the exposure to the exogenous 15 sources of the NDMA; true?</p> <p>16 MR. SLATER: Objection. You 17 can answer.</p> <p>18 A I don't think that that's 19 really known at this point.</p> <p>20 Q And you don't have an 21 opinion about that, therefore; correct?</p> <p>22 MR. SLATER: Objection. You 23 can answer.</p> <p>24 A I leave open the 25 possibilities that it could be more or</p>
<p style="text-align: right;">Page 227</p> <p>1 MR. SLATER: Objection. You 2 can answer.</p> <p>3 A In my opinion, having looked 4 at the literature on endogenous 5 formation, I don't think that there is a 6 solid evidentiary basis to make that 7 comparison. As I said, I saw widely 8 varying models as to how much endogenous 9 NDMA is produced.</p> <p>10 And furthermore, there is no 11 direct study. There is no measurement of 12 it. There's only a model of inference. 13 And they vary greatly.</p> <p>14 Q Do you know the amount of 15 endogenous -- or do you have an opinion 16 whether the amount of endogenously 17 produced NDMA is more or less than the 18 FDA's stated acceptable intake levels of 19 96 ngs per day in the Valsartan 20 320-milligram tablets?</p> <p>21 MR. SLATER: Objection to 22 the question. You can answer.</p> <p>23 A I think almost all sources 24 certainly think it's more than 25 96 nanograms per day. I haven't seen any</p>	<p style="text-align: right;">Page 229</p> <p>1 less toxic.</p> <p>2 Q In other words, you do not 3 have an expert opinion on that topic; 4 correct?</p> <p>5 MR. SLATER: Objection. You 6 can answer.</p> <p>7 A Just to clarify, the 8 question is, on whether endogenous versus 9 exogenous is more or less dangerous?</p> <p>10 Q Yes.</p> <p>11 A Well, not to a reasonable 12 degree of scientific certainty.</p> <p>13 Q Okay. Fair enough. 14 Let's look at the -- let's 15 see. So the next exhibit will be --</p> <p>16 MR. SLATER: What was the 17 EMA document?</p> <p>18 MS. COHEN: 10. We'll mark 19 as 11 the original Jakiszyn. 20 (The above-referred-to 21 document was marked as Exhibit 11 for 22 identification, as of this date.)</p> <p>23 Q And I'll refer you to the 24 cites. This is Footnote 36 in the 25 report. And that's the one that was</p>

<p>1 originally there which we got last night. 2 And then page 16 is I think where it's 3 cited. And it's not really an 4 appropriate cite right there. Is that 5 what you were telling me before? 6 MR. SLATER: Objection. 7 A Yes, correct. On 16, the 8 reference should not go to this report. 9 It belongs to the other Jakuszyn paper. 10 Q And you already told me that 11 it's still applicable to the report 12 overall -- let's look at under the 13 discussion part. And it says -- this is 14 1499. It's the page on Discussion. 15 "This is the first study 16 reporting relationships between both 17 endogenous and exogenous exposures to 18 NOCs and GC risk. The exposure of NDMA 19 from food was less than 1 per day, 20 whereas that from ENOC was 93 per day 21 (Table 1)." 22 And then it says, "We found 23 that non-cardia GC was positively 24 associated with ENOC exposure but not 25 with dietary NDMA."</p>	<p>Page 230</p> <p>1 multiple studies with respect to 2 endogenous formation of NDMA. And the 3 results varied greatly. There are 4 studies I believe that are in Hruday or 5 referenced at least in Hruday which come 6 up with numbers like the one you just 7 said. There are others like Choi, which 8 are more on the order -- it's about 9 1,000, 1,300 nanograms per day. 10 But irrespective of what the 11 baseline is, we still have the dietary 12 studies, which fully weighted, you know, 13 looking at them in their totality show an 14 effect for doses of NDMA, you know, 15 really getting into a little over 16 100 nanograms per day. 17 Q But you've seen this 18 article; you read that part of 19 it --right?-- when you read it or maybe 20 not? 21 A Yes. 22 Q Again, you cited to it 23 originally? 24 A Yes. 25 Q And you knew from this that</p>
<p>1 Do you see that? 2 A I do. 3 Q And then if you turn to 4 Table 1, which shows that the mean daily 5 exposure to endogenously produced 6 N-nitroso compounds to be 93, is that MG? 7 A Microgram. 8 Q Per day. Thank you. 9 Can you convert what 93.05 10 microgram per day is in terms of ng per 11 day? 12 A Sure. 93,000. 13 Q And, of course, 93.05 would 14 be 93,050 to be exact; right? 15 A Yes. 16 Q Did you know -- and, again, 17 there's been some reports on this -- that 18 the endogenous production of NDMA 19 estimated to result in exposures that are 20 approximately 1,875 higher than the 21 highest estimated levels of exogenous 22 exposure due to the preformed NDMA in the 23 food, drinking water and such? Do you 24 read that? 25 A Well, as I said, I looked at</p>	<p>Page 231</p> <p>1 there were studies -- this says this is 2 the first study reporting relationships 3 that show that the endogenous biochemical 4 processes are far greater in terms of 5 contribution to genome mutation than 6 exogenous. You came across this and in 7 other studies like this; right? 8 MR. SLATER: Objection. You 9 could answer. 10 A Yeah. As I said, there are 11 studies that show a lot of endogenous 12 formation. There are studies that show 13 much less. And these are all estimates. 14 These are models. 15 Q You were not given the 16 report -- we may mark it at some point -- 17 the report of Lewis Chodosh, M.D., Ph.D.? 18 A No. 19 Q Have you heard of him? 20 A No. 21 Q Do you know who he is in 22 this case? 23 A I think you mentioned him as 24 a defense expert earlier. 25 Q Cancer biologist.</p>

1 A Okay. 2 Q That's not your area of 3 expertise; correct? 4 MR. SLATER: Objection. You 5 can answer. 6 A I mean I think I said 7 multiple times, I am an expert on cancer. 8 I am not a practicing cancer biologist. 9 Q You're not trained as a 10 cancer biologist, are you, Doctor? 11 MR. SLATER: Objection. You 12 can answer. 13 A I have extensive training in 14 cancer biology. 15 Q You didn't take any 16 schooling or extra training on cancer 17 biology, did you? 18 MR. SLATER: Objection. You 19 could answer. 20 A It was certainly covered in 21 medical school. 22 Q Putting aside medical 23 school -- 24 A Putting aside my graduate 25 school? Okay.	Page 234	Page 236
1 Q Well, people learn about 2 pathology in medical school, don't they? 3 A Yeah. 4 Q Maybe a pathologist does it? 5 MR. SLATER: No, counsel. 6 Are you arguing with the witness or 7 do you have a question for him? 8 MS. COHEN: No. I'm asking 9 him. 10 Q People who go to medical 11 school want to learn about pathology; 12 right? 13 A Yes. 14 Q Doesn't make them a 15 pathologist? 16 A Doesn't make them a 17 practicing pathologist. I would hope 18 they have some knowledge of pathology. 19 Q And cancer biology, that 20 requires extra schooling and education. 21 Have you had any of that? 22 MR. SLATER: Objection. You 23 can answer. 24 A I've had a lot of education 25 on cancer biology. I read articles.	Page 235	1 I've written articles related to cancer 2 biology. I am not a cancer biologist in 3 the sense of, you know, maintaining a 4 research laboratory devoted strictly to 5 cancer biology research. 6 Q But you haven't had any 7 training beyond medical school and cancer 8 biology. I'm not talking about reading. 9 Do you have any advanced 10 degrees? 11 MR. SLATER: Objection. You 12 can answer. 13 A Advanced degrees other than 14 my M.D.? 15 Q Yes. 16 A I do not. 17 Q Any specific courses or 18 training in cancer biology, beyond your 19 M.D? 20 MR. SLATER: Objection. You 21 can answer. 22 A During my training, topic of 23 cancer biology came up frequently. And I 24 was educated on it, probably nearly a 25 daily basis.

<p>1 could answer.</p> <p>2 A I think you're using the 3 words "cancer biologist" as if it's some 4 set-in-stone thing that to be a cancer 5 biologist, you are -- you know, this is 6 exactly what describes a cancer 7 biologist. I certainly have deep 8 knowledge about cancer biology.</p> <p>9 Q Did you ever win any awards 10 or honors in cancer biology?</p> <p>11 MR. SLATER: Objection. You 12 can answer.</p> <p>13 A No.</p> <p>14 Q Still in your report, let's 15 look at page 3. And another reference I 16 want to look at, I think it's the next 17 sentence.</p> <p>18 "NDMA (and related compounds 19 such as NDEA) have been studied 20 extensively in animal models, where it 21 has been shown to be a potent 22 carcinogen."</p> <p>23 Is that your sentence there?</p> <p>24 A Yes.</p> <p>25 Q And you cite to No. 5 for</p>	<p>Page 238</p> <p>1 Q It's one of them?</p> <p>2 MR. SLATER: Objection. You 3 can answer.</p> <p>4 A Sure. Well, the main one is 5 a monograph. It's about 350 pages.</p> <p>6 Q The good news is we'll 7 probably get to that one.</p> <p>8 A Okay.</p> <p>9 Q So hang tight.</p> <p>10 You've read this one.</p> <p>11 Obviously, you cited to it;</p> <p>12 right?</p> <p>13 A Yes.</p> <p>14 Q So I have a couple of things 15 to point out on this.</p> <p>16 This is, I guess -- Lancet 17 is a very well-known journal, of course; 18 right?</p> <p>19 A Yes.</p> <p>20 Q One that's respected?</p> <p>21 A Yes.</p> <p>22 Q And this article, what it 23 says, let's look at page 1 over on the 24 right-hand column.</p> <p>25 And it says, "The evidence</p>
<p>1 that. That is the IARC monograph, I 2 believe. 2020. And let's make sure I 3 have that right.</p> <p>4 So on page 34 of your report 5 No. 5 is the IARC: Carcinogenicity, and 6 the Lancet, 2020, just to make sure we're 7 all on the same page as we go through 8 this.</p> <p>9 I take it you have not read 10 this article before, getting involved in 11 this litigation as a litigation expert; 12 correct?</p> <p>13 A Correct.</p> <p>14 (The above-referred-to 15 document was marked as Exhibit 12 for 16 identification, as of this date.)</p> <p>17 Q I'm going to hand you 18 Exhibit 12.</p> <p>19 And this is one of the 20 things that you referred us to earlier 21 today; right?</p> <p>22 MR. SLATER: Objection. You 23 can answer the question.</p> <p>24 A Sure. This is not the main 25 IARC document on NDMA.</p>	<p>Page 239</p> <p>1 in humans was inadequate as aniline's 2 effects could not be differentiated from 3 those of other bladder carcinogens in the 4 most informative studies."</p> <p>5 You see that?</p> <p>6 A Yeah. I'm sorry to do this.</p> <p>7 This is a little embarrassing. But I 8 have to admit it, this is the wrong cite.</p> <p>9 It's the wrong IARC cite. I meant to say 10 the main IARC monograph. So 19 was what 11 that should be cited to.</p> <p>12 Q So you want to cite to 19?</p> <p>13 A Yes.</p> <p>14 Q Which is on page 34?</p> <p>15 A Yes.</p> <p>16 Q Which I think we'll probably 17 get to in any event.</p> <p>18 A This is not 19 nitrosamine-related. I don't think I 20 should have included this. I think every 21 reference -- every cite to this should 22 really be to 19.</p> <p>23 Q Well, first of all --</p> <p>24 A These are aromatic amines.</p> <p>25 It's not the same thing.</p>

1 Q But they're related? 2 A You know, they're chemically 3 related, but they're not the same. 4 Q You understand why I'm going 5 through this? You cite to this. 6 A It was a mistake on my part. 7 MR. SLATER: There's nothing 8 for you to add. She's telling you 9 something. 10 Q On page 2, let's go to the 11 other cite I want to go to. It says -- 12 let's see. 13 Again, on the left-hand 14 column, it says, "The evidence in humans 15 was inadequate, consisting solely of a 16 bladder cancer case series with 17 concomitant exposure to other bladder 18 carcinogens." 19 That's what this article 20 says; right? 21 A Yeah, but not talking about 22 nitrosamines. 23 Q Well, it's talking about 24 nitro -- what's the word? -- anisoles? 25 A Yeah.	Page 242  1 Q And do you agree that it's 2 classified as 2A as you note there? 3 A Yes. 4 Q And this is also, I believe, 5 Reference 6 which we see on page 3 on the 6 bottom there. Let's pull out this IARC. 7 Is this the one you wanted 8 to look at, this IARC? 9 MR. SLATER: This one? 10 Objection. 11 MS. COHEN: That's what he 12 said. 13 Q Is this the IARC that you 14 wanted to cite to? 15 A Let's cite to 19, 19 IARC. 16 Q We'll go through this one 17 first. This is the one. 18 6 is listed in your report; 19 right? 20 A Yes. That might be right. 21 There's similar information involved. 22 Q And here is the IARC 23 monograph, Exhibit 13. 24 (The above-referred-to 25 document was marked as Exhibit 13 for
1 Q And then on page 2, let's go 2 to the last sentence of this. This 3 article that you cited to, it says, "The 4 evidence for cancer in humans was 5 inadequate as no data were available"; 6 correct? 7 A Again, not related to NDMA, 8 but, yes, that's what it says. 9 Q And it also says -- it says, 10 "A working group of 19 scientists were 11 involved here and that the assessments 12 will be published in Volume 127 of the 13 monographs" in the top part. 14 A Okay. 15 Q So further down, let's see, 16 on page 3, I'm going to go back to your 17 report. And I'll put aside your 18 Reference 5. 19 And you also mentioned the 20 World Health Organization earlier today 21 and, of course, the IARC which is an arm 22 of the World Health Organization you're 23 talking about here on page 3. Do you see 24 that? 25 A Yes.	Page 243  1 identification, as of this date.) 2 Q This is your Reference 6; 3 correct? 4 A Yes. 5 Q And 2A, do you agree, is 6 defined as IARC states that Class 2A is 7 appropriate classification for a 8 potential carcinogen when there is 9 limited evidence of carcinogenicity in 10 humans and sufficient evidence of 11 carcinogenicity in experimental animals? 12 A Are you reading that 13 directly from IARC? 14 Q Yes. 15 A I'd just like to see it. 16 Q You got it. I understand. 17 I had flagged it last night. This is in 18 your Reference 6, page 30. Just tell me 19 when you're there, sir. 20 A Okay. 21 Q And, again, this is -- if we 22 look back in your report, you say -- 23 classifies NDMA as Class 2A. Reference 6 24 is what we're looking at. And then we 25 look at page 30 to see what 2A says, not

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<p>1 just the highlight and not just the      2 header. It says, "This category is used      3 when there's limited evidence of      4 carcinogenicity in humans and sufficient      5 evidence of carcinogenicity in      6 experimental animals. In some cases an      7 agent may be classified in this category      8 where there's inadequate evidence of      9 carcinogenicity in humans and sufficient      10 evidence of carcinogenicity in      11 experimental animals and strong evidence      12 that the carcinogenesis is mediated by a      13 mechanism that also operates in humans."</p> <p>14       And it goes on to say,      15 "Exceptionally, an agent may be      16 classified in this category solely on the      17 basis of limited evidence of      18 carcinogenicity in humans."</p> <p>19       And you understood that;      20 right?</p> <p>21      A    Yes.</p> <p>22      Q    And that's what you meant      23 when you said 2A in here; right?</p> <p>24      A    Yes.</p> <p>25      Q    Now, the part I'm curious</p>	<p>Page 246</p> <p>1 induced tumors in all species when fed at      2 doses of 1 to 13-milligram/kilogram bw      3 per day for life"; correct?</p> <p>4      A    That is what it says.</p> <p>5      Q    And that concentration, if      6 extrapolated to humans, would mean in a      7 50-kilogram, 110-pound human or adult      8 getting from 50,000 micrograms to 650,000      9 micrograms per day in order to observe      10 that effect?</p> <p>11     A    Sorry. What was that?</p> <p>12     Q    If you want to extrapolate      13 that and figure out what is that      14 concentration in humans, it would be in a      15 110-pound adult, 50,000 micrograms to      16 650,000 micrograms per day. You know      17 that that's true?</p> <p>18     MR. SLATER: Objection. You      19 can answer.</p> <p>20     A    I don't know that to be      21 true.</p> <p>22     Q    You haven't done that      23 calculation?</p> <p>24     A    Correct.</p> <p>25     Q    Wouldn't that have been</p>
<p>1 on, page 3 in your report, if we go back      2 to that, where it says, "In its monograph      3 on processed meats, IARC refers to NDMA      4 as 'genotoxic compounds.'" You have      5 quotes there.</p> <p>6       Is that in here, this      7 article?</p> <p>8      A    Yes.</p> <p>9      Q    Can you tell us where it is?</p> <p>10     A    No. It would take -- I'd      11 have to -- if we have an electronic      12 version, we can probably search through      13 it.</p> <p>14     Q    We can look, we being      15 Bardia.</p> <p>16     And did you read the entire      17 document here? I know it's many pages.</p> <p>18     A    No.</p> <p>19     Q    On page 421 in this article,      20 421, about halfway down, I'll let you get      21 there.</p> <p>22     A    Okay.</p> <p>23     Q    It says, "NDMA has been fed      24 to mice, rats, hamsters, guinea-pigs,      25 rabbits, dogs, pigs and monkeys. It</p>	<p>Page 247</p> <p>1 important in this article that you're      2 citing to in terms of IARCs that you've      3 cited to multiple times in your report to      4 know how you could extrapolate to humans,      5 what we're talking about?</p> <p>6      A    Well, there are several      7 problems with that. First is, you can't      8 just -- humans are -- there are      9 differences between humans and animals.      10 So there are similarities, and there are      11 differences. And doses might not be      12 easily extrapolated from one to the      13 other.</p> <p>14     Secondly, I mean this is      15 what you do if you're aggressively trying      16 to give them cancer. So I mean no one is      17 saying that the purpose of these      18 medicines was to give people cancer,      19 whereas the purpose of these experiments      20 is to give the animals cancer.</p> <p>21     So if you want to be      22 absolutely sure that everybody who took      23 it got cancer, maybe you would try to run      24 that calculation and do it. But I don't      25 think that's what anyone is attempting.</p>

<p style="text-align: right;">Page 250</p> <p>1 Q So the next paragraph 2 underneath that says, "NDMA has been 3 administered orally to mice, rats, 4 hamsters, guinea-pigs, rabbits and fish. 5 All species were susceptible to increased 6 tumor formation in doses of 0.4 to 7 4-milligram/kilogram bw per day. Tumors 8 were the most prevalent."</p> <p>9 Again, there, did you make 10 any extrapolation in terms of what that 11 would mean in humans?</p> <p>12 A Well, the EMA and the FDA 13 did. So I read that in their reports.</p> <p>14 Q Did you figure out that this 15 means 20,000 micrograms to 200,000 16 micrograms per day to get that exposure?</p> <p>17 MR. SLATER: Objection. You 18 can answer.</p> <p>19 A Again, you can't just 20 extrapolate so easily between animals and 21 humans. The purpose of these experiments 22 was to give these animals cancer. And, 23 finally, the EMA and the FDA did do those 24 calculations based on the TD50 in the 25 animal studies. And that's how they came</p>	<p style="text-align: right;">Page 252</p> <p>1 Just tell me when you're there. 2 A Sure. 3 Q You could put that aside if 4 it's uncomfortable on your lap there. 5 So page 4 -- and you cite to 6 7 here -- that is the ICH M7 which we'll 7 get to in a minute. This talks about a 8 cohort of concern which they define as 9 high potency. Here, you're talking about 10 ICH, high potency mutagenic compounds. 11 Do you see that?</p> <p>12 A I do, yes.</p> <p>13 Q And you agree that not all 14 the compounds and cohort of concern are 15 shown to be carcinogenic to humans; 16 correct?</p> <p>17 MR. SLATER: Objection. You 18 can answer.</p> <p>19 A I don't have an opinion on 20 that.</p> <p>21 Q You're just not sure sitting 22 here right now?</p> <p>23 A Right.</p> <p>24 Q And, for example, all 25 nitrosamines are included in a cohort of</p>
<p style="text-align: right;">Page 251</p> <p>1 up with their -- with some of their 2 estimates.</p> <p>3 Q We're going to get to those 4 too.</p> <p>5 You would agree that those 6 levels of NDMA and NDEA are hundreds of 7 times higher than the exposure issued in 8 the Valsartan products? Do you know 9 that?</p> <p>10 A I don't recall what levels 11 it said.</p> <p>12 MR. SLATER: Objection.</p> <p>13 Q Well, I'll tell you what 14 they are if you want to know.</p> <p>15 There are 50,000 micrograms 16 to 650,000 micrograms, 20,000 micrograms 17 to 200,000 micrograms. Those would be 18 hundreds of times higher; true?</p> <p>19 A Those numbers for what they 20 mean -- and I don't know what they mean 21 exactly in this context -- are higher 22 than what was actually found in the 23 pills.</p> <p>24 Q On page -- let's go to 25 another point on page 4 of your report.</p>	<p style="text-align: right;">Page 253</p> <p>1 concern, but you know that not all 2 nitrosamines are carcinogenic? You know 3 that; right?</p> <p>4 A I know that some are more 5 potent than others. I know that there 6 are non-volatile ones. But probably, 7 that's true.</p> <p>8 Q You just don't know, sitting 9 here; right?</p> <p>10 A I think it's probably true.</p> <p>11 Q You've been studying this 12 literature in your report in this case, 13 and it's the first time you're reading 14 these materials; right?</p> <p>15 MR. SLATER: Objection. You 16 could answer.</p> <p>17 A I mean most of them, I've 18 read for the first time in conjunction 19 with this case.</p> <p>20 Q The IARC 2020 monograph, you 21 never read that before this case, did 22 you?</p> <p>23 A No.</p> <p>24 Q The IARC 2018 monograph, you 25 never read that before this case, did</p>

<p>1 you?</p> <p>2 A Nope.</p> <p>3 Q The IARC 2019, which I know</p> <p>4 you want to get to, you haven't read</p> <p>5 that, have you, before this?</p> <p>6 MR. SLATER: Objection.</p> <p>7 A No.</p> <p>8 Q The ICH M7, you didn't read</p> <p>9 that before this case, did you?</p> <p>10 A I did not.</p> <p>11 Can we do a break?</p> <p>12 Q Yes, absolutely.</p> <p>13 THE VIDEOGRAPHER: We are</p> <p>14 now off the record. The time is</p> <p>15 2:52 p.m. Eastern Time.</p> <p>16 (A short recess was taken.)</p> <p>17 THE VIDEOGRAPHER: We are</p> <p>18 back on the record. The time is</p> <p>19 3:11 p.m. Eastern Time.</p> <p>20 Q So we're back on. We're</p> <p>21 kind of moving through some of these</p> <p>22 references. Let's see where I left off.</p> <p>23 This is the ICH M7 that we</p> <p>24 have on page 4 of your report.</p> <p>25 A Yes.</p>	<p>Page 254</p> <p>1 Q And you understand that ICH</p> <p>2 has brought together regulatory</p> <p>3 authorities, pharmaceutical industry</p> <p>4 authorities to discuss some of these</p> <p>5 scientific and technical issues,</p> <p>6 collaborative group?</p> <p>7 MR. SLATER: Objection. You</p> <p>8 can answer.</p> <p>9 A Yeah. Sounds about right.</p> <p>10 Q And have you read this --</p> <p>11 and I'll call it the M7, if that's okay</p> <p>12 with you -- in full?</p> <p>13 A In considerable detail.</p> <p>14 Q Now, what it says on page 6</p> <p>15 is -- let's see -- it states that --</p> <p>16 Class 2 impurities like nitrosamines are</p> <p>17 "known mutagens with unknown carcinogenic</p> <p>18 potential."</p> <p>19 You see that?</p> <p>20 A I do see that as a</p> <p>21 definition of a Class 2 compound.</p> <p>22 Q And it actually says, again,</p> <p>23 they have unknown carcinogenic potential.</p> <p>24 And it goes on to say, "Bacterial</p> <p>25 mutagenicity, positive, no rodent</p>
<p>1 Q I may have already said this</p> <p>2 before. Reference 7. I'm giving you</p> <p>3 Exhibit 14.</p> <p>4 (The above-referred-to</p> <p>5 document was marked as Exhibit 14 for</p> <p>6 identification, as of this date.)</p> <p>7 Q You cite to this -- it's on</p> <p>8 the bottom of 3, top of 4. It says</p> <p>9 "International Counsel for Harmonisation</p> <p>10 of Technical Requirements for</p> <p>11 Pharmaceuticals for Human Use (ICH)</p> <p>12 includes nitrosamines in a cohort of</p> <p>13 concern -- that we talked about before --</p> <p>14 which they define as high potency</p> <p>15 mutagenic compounds. A mutagenic</p> <p>16 compound is one which can cause mutations</p> <p>17 in DNA and can lead to cancer."</p> <p>18 Those were your words;</p> <p>19 right?</p> <p>20 A Correct.</p> <p>21 Q You're not familiar with</p> <p>22 ICH, are you, in general?</p> <p>23 A I am familiar with them.</p> <p>24 Q Now you are?</p> <p>25 A Correct.</p>	<p>Page 255</p> <p>1 carcinogenicity data."</p> <p>2 MR. SLATER: What page are</p> <p>3 you on?</p> <p>4 MS. COHEN: Page 6.</p> <p>5 MR. SLATER: 6, okay.</p> <p>6 MS. COHEN: Did I say that</p> <p>7 wrong?</p> <p>8 MR. SLATER: No. I misheard</p> <p>9 you when you said the page number.</p> <p>10 Q What you said in your report</p> <p>11 was "well-known carcinogens"; right? You</p> <p>12 see that on the top of page 4?</p> <p>13 A Yes. I see that there.</p> <p>14 Q But what this says is</p> <p>15 actually known mutagens or unknown</p> <p>16 carcinogenic potential; correct?</p> <p>17 A Well, as I sit here right</p> <p>18 now, I don't recall if ICH called this</p> <p>19 Class 2 or Class 1.</p> <p>20 Q We may put this to the side</p> <p>21 and come back to it.</p> <p>22 A Okay.</p> <p>23 Q So let's move to -- we'll</p> <p>24 put this aside -- Reference 11 which is</p> <p>25 on page 5 of your report.</p>

<p style="text-align: right;">Page 258</p> <p>1 MR. SLATER: You said page 5 2 of his report?</p> <p>3 MS. COHEN: Yes. Page 5 of 4 his report. And it'll be Reference 5 11 which is the Thresher article.</p> <p>6 Q Do you recall that one?</p> <p>7 A Yes.</p> <p>8 Q This relates to the NDEA. 9 You say on the top of page 5, first full 10 paragraph, you say, "NDEA also identified 11 in Valsartan and according to 12 researchers, using both bacterial and 13 rodent experimental data, may be the most 14 potent carcinogen of any known 15 nitrosamine," citing to this Reference 11 16 which is the Thresher article. That is 17 Exhibit 15.</p> <p>18 (The above-referred-to 19 document was marked as Exhibit 15 for 20 identification, as of this date.)</p> <p>21 Q Do you recall reading this 22 article?</p> <p>23 A Yes.</p> <p>24 Q Page 3, bottom of the 25 right-hand column, it talks about, "NDEA</p>	<p style="text-align: right;">Page 260</p> <p>1 could be the most potent; is that what 2 you said there?</p> <p>3 A I believe that is consistent 4 with what the article says. It goes 5 against the idea that all nitrosamines 6 would be carcinogenic.</p> <p>7 MR. SLATER: Objection. You 8 can answer.</p> <p>9 A A, I did not make that 10 statement. And B, I agree. This paper 11 shows that 82 percent are, and 18 percent 12 aren't.</p> <p>13 Q And, again, other than 14 looking at the materials that were 15 provided to you in this case that we're 16 going through, you've never undertaken 17 any independent research of NDMA or NDEA; 18 true?</p> <p>19 MR. SLATER: Objection. You 20 can answer.</p> <p>21 A Outside of litigation work 22 and what is represented here, I have not.</p> <p>23 Q Much of the extensive 24 studies on NDMA have focused on the 25 animal studies. You agree with that;</p>
<p style="text-align: right;">Page 259</p> <p>1 is the most potent nitrosamine for which 2 carcinogenicity data is available" is 3 what --</p> <p>4 A I'm not finding that.</p> <p>5 Q I'm sorry. It's right down 6 here. Do you see that?</p> <p>7 A Yes. I see it.</p> <p>8 Q On the next page, page 4, it 9 says under Discussion, talking about the 10 study in the article, "This has shown 11 that despite the majority of nitrosamines 12 being carcinogenic, approximately 13 18 percent of the data set resolved as 14 non-carcinogenic based on the expanded 15 data."</p> <p>16 Do you see that?</p> <p>17 A Let me just read and 18 familiarize myself. Okay. Yes. 19 82 percent of nitrosamines are 20 carcinogenic.</p> <p>21 Q Right.</p> <p>22 And 18 percent of this 23 article are not; correct?</p> <p>24 A Yes.</p> <p>25 Q Your reference to NDEA, it</p>	<p style="text-align: right;">Page 261</p> <p>1 correct?</p> <p>2 MR. SLATER: Objection. You 3 can answer.</p> <p>4 A Yes. When we're talking 5 about a mutagenic compound, you cannot 6 ethically give this to people, really to 7 any extent. It would be unethical. And 8 nobody would sign up for it.</p> <p>9 Q I want to go to next, talk 10 about some of the FDA information.</p> <p>11 A Okay.</p> <p>12 Q Because I think we talked 13 about that a little bit before. Let's 14 pick up on that now on what the FDA had 15 to say.</p> <p>16 And starting on page 4 of 17 your report, I think it's in the first 18 full paragraph, second paragraph of the 19 page, we talked a little bit about this 20 before. But I want to get to some of the 21 cites. The FDA set the maximum daily 22 exposure to NDMA. These are the numbers 23 we went over before. And you have a 24 number of references here that you cite 25 to, 9 and 10. 10 is FDA.</p>

<p>1           MR. SLATER: Go ahead. I'm 2 sorry. I don't want to object. 3 But -- 4           MS. COHEN: I'm going too 5 fast? 6           MR. SLATER: No. I thought 7 you were reading one paragraph. And 8 then you were citing references to a 9 different one. I'm not trying to 10 interrupt. 11          Q You cited to FDA references; 12 correct? 13          A Yes. 14          Q Did all of the FDA 15 references that you cite to come to you 16 from Mr. Slater? 17          A No. 18          Q Did you pull some yourself 19 from the FDA? 20          A I did. 21          Q And you would agree it's 22 important to consider all the FDA had to 23 say; correct? 24          A I read everything that the 25 FDA said that I could find and took it in</p>	<p>Page 262</p> <p>1           Q And what it says here, if 2 you look at the bottom of the page, it 3 talks about, "The acceptable intake is a 4 daily exposure to a compound such as 5 NDMA, NDEA or MMBA that approximates a 6 1:100,000 cancer risk up to 70 years 7 exposure." 8           Have you seen that before? 9          A I have. 10         Q Had you read this specific 11 document before? 12         A I did. 13         Q And do you agree having seen 14 this now that the 96 nanograms of NDMA is 15 the daily acceptable intake for Valsartan 16 320-milligram tablet? 17         A I believe it's an interim 18 limit, actually. I think the FDA's 19 guidance is to get it down to 20 non-detectable. But in the interim, they 21 will allow up to 96 nanograms. 22         Q Well, what you said on page 23 4 of your report is the U.S. Food and 24 Drug Administration, FDA, has set a 25 maximum daily exposure limit to NDMA at</p>
<p>1 context of all the other information that 2 I was finding. 3          Q Now, on page 4, you used the 4 term "maximum daily exposure limit"; 5 right? 6          A I did. 7          Q But the FDA words are really 8 acceptable intake, aren't they? 9          A As I sit here right now, I 10 don't quite recall. If you show me the 11 verbiage, I'd be happy to look at it. 12         Q Let's go to the 13 February 28th, 2019 FDA press release. 14         (The above-referred-to 15 document was marked as Exhibit 16 for 16 identification, as of this date.) 17         Q I'm going to give you 18 Exhibit 16. And if you look to -- 19         MR. SLATER: Is this the one 20 that starts -- it says "FDA Warns 21 Mylan for CGMP Deviations" ? 22         MS. COHEN: No. About six 23 pages in, the one that starts with 24 February 28th, 2019. 25         A Okay. I'm on that one.</p>	<p>Page 263</p> <p>1           96 nanograms per day or 0.3 ppm. Do you 2 see that? 3          A I do. 4          Q You don't say interim, do 5 you? 6          A Well, it says quite clearly 7 here, interim. 8          Q In your report? 9          A No. The FDA does. 10         Q But your report doesn't call 11 it an interim; you talk about maximum 12 daily exposure limit, but really, it's -- 13 the phrase is the acceptable -- the 14 acceptable intake. 15         MR. SLATER: Objection. You 16 could answer. 17         A Sure. Right above that, you 18 see interim on that. So it's interim 19 acceptable intake. 20         Q Which you don't have in your 21 report? 22         A I could have used that 23 phraseology. 24         Q And then this also says, as 25 we talked about, the 1:100,000 cancer</p>

1 risk after 70 years exposure.  
 2 You've seen that before,  
 3 that statement?  
 4 A I have.  
 5 Q You don't disagree with this  
 6 assessment, do you?  
 7 MR. SLATER: Objection. You  
 8 can answer.  
 9 A I agree that it's the FDA's  
 10 estimate. Doesn't necessarily mean it's  
 11 true. And for the 1:100,000 person, it  
 12 really sucks. But I don't disagree  
 13 specifically. I agree it's the best  
 14 estimate.  
 15 Q Again, you're not a  
 16 biostatistician; correct?  
 17 A I am not.  
 18 Q And let's go to the next FDA  
 19 document. This would be 28.  
 20 (The above-referred-to  
 21 document was marked as Exhibit 17 for  
 22 identification, as of this date.)  
 23 Q So I take it you've seen  
 24 this one at some point too, another FDA?  
 25 A Looks familiar.

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1 Q And the FDA gov site, as we  
 2 say. And turn to page -- get past the  
 3 pictures, maybe three, four pages in.  
 4 And, again, this is what the FDA is  
 5 putting out at the time of this article  
 6 to the public to reassure, provide  
 7 information, whatever you want to say.  
 8 And the fourth bullet here,  
 9 it says, "Nitrosamine impurities may  
 10 increase the risk of cancer if people are  
 11 exposed to them above acceptable levels  
 12 and over long periods of time, but a  
 13 person taking a drug that contains  
 14 nitrosamines at-or-below the acceptable  
 15 daily intake limits every day for 70  
 16 years is not expected to have an  
 17 increased risk of cancer."  
 18 You see that?  
 19 A I see that.  
 20 Q That's what the FDA told --  
 21 I think you cited to the FDA earlier.  
 22 That's what the FDA was telling the  
 23 public; correct?  
 24 A Yes.  
 25 Q And you don't disagree with

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1 that; you don't have any reason to  
 2 disagree with those statistics; correct?  
 3 MR. SLATER: Objection. You  
 4 can answer.  
 5 A I accept that that method  
 6 that FDA used to come up with that method  
 7 is probably close to accurate.  
 8 Q Then it says in the next  
 9 bullet on the next page that "Patients  
 10 taking prescription medications with  
 11 potential nitrosamine impurities should  
 12 not stop taking their medications.  
 13 Patients should talk to their health care  
 14 professionals about concerns and other  
 15 treatment options."  
 16 I take it you read that?  
 17 A I do. I did.  
 18 Q You certainly agree with  
 19 that; that's something that a patient  
 20 should consult with their doctors about;  
 21 right?  
 22 A I certainly agree that  
 23 patients should talk to their doctors. I  
 24 don't believe that they should continue  
 25 taking their medications.

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1 Q But, again, you don't  
 2 prescribe these medications; true?  
 3 A That's true.  
 4 Q Other types of doctors and  
 5 other specialties do the prescribing;  
 6 correct?  
 7 A Correct.  
 8 Q And that would be people  
 9 like internal medicine doctors,  
 10 hypertension experts, that sort of thing;  
 11 correct?  
 12 A Yeah. Nephrologists.  
 13 Q And you would defer to  
 14 those --  
 15 A Cardiologists.  
 16 Q -- doctors in terms of their  
 17 assessment in valuation of a risk versus  
 18 benefit; correct?  
 19 A Generally, yeah.  
 20 Q Turn to another article.  
 21 This will be 18.  
 22 (The above-referred-to  
 23 document was marked as Exhibit 18 for  
 24 identification, as of this date.)  
 25 Q So this is another one that

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<p>1 the FDA put out on April 14th, 2019 by 2 Scott Gottlieb, who was the former 3 commissioner of the FDA.</p> <p>4 You've seen this one, I take 5 it?</p> <p>6 MR. SLATER: This is 7 Exhibit 18; right?</p> <p>8 MS. COHEN: Yes.</p> <p>9 A I don't specifically recall 10 reading this one.</p> <p>11 Q It says that, few pages 12 in -- if you could turn to the paragraph 13 starting with, "Patients should 14 continue," it says, "Patients should 15 continue taking their medicine until 16 their pharmacist provides a replacement 17 or their doctor provides an alternative 18 treatment option even if they learn that 19 their ARB medicine is recalled. The risk 20 associated with abruptly discontinuing 21 the use of these important medicines far 22 outweighs the low risks that our 23 scientists estimate to be associated with 24 continuing medicine until the patient's 25 doctor or pharmacist provides a safe</p>	<p>Page 270</p> <p>1 a comprehensive and constant working 2 group, a multidisciplinary team of 3 chemists, toxicologists, physicians, 4 pharmacists, communication specialists, 5 investigators, laboratory staff to 6 address this issue?</p> <p>7 A Yes.</p> <p>8 Q And you didn't consult on 9 this issue for the FDA, I take it; 10 correct?</p> <p>11 A Correct.</p> <p>12 Q You certainly aren't 13 positioned to disagree with the numerous 14 FDA scientists on these issues -- 15 correct? -- in terms of the risks being 16 very low?</p> <p>17 A Well, I mean I have done my 18 own review of the medical scientific 19 literature. And I don't think that the 20 risk is that low. I think that we see 21 particularly from the Al-Kindi article 22 that even virtually no -- very little 23 time for latency. There was really a 24 rather significant increase in the risk 25 of neoplasms associated with Valsartan.</p>
<p>1 replacement or a different treatment 2 option."</p> <p>3 And it says, "Despite these 4 very low risks," the next paragraph.</p> <p>5 Again, it's kind of more of 6 the same from the FDA; correct?</p> <p>7 A Well, I mean this, broadly 8 speaking, patients who get 9 anti-hypersensitive drugs are at an 10 increased risk of a heart attack. So 11 these people don't take Valsartan 12 recreationally. They take it to prevent 13 cardiac events. They certainly have 14 every reason to expect and believe that 15 their drugs will be free of contaminants. 16 And this is a huge breach of their trust. 17 But whether they should stop 18 abruptly, the FDA is saying not to stop 19 abruptly but to go to your pharmacist and 20 go to your doctor to get an alternative.</p> <p>21 MS. COHEN: I'll move to 22 strike that.</p> <p>23 Q I appreciate your response. 24 Let me ask another question 25 which is, you understand that the FDA had</p>	<p>Page 271</p> <p>1 So I think that it will take time for all 2 the studies to be conducted and for final 3 answers to be known. But I don't think 4 that risk is very low.</p> <p>5 Q So you disagree with the FDA 6 and the statement here and the 7 scientists?</p> <p>8 A Which statement?</p> <p>9 Q This statement from 2019, 10 which we've marked as Exhibit 18, you 11 would disagree with the FDA and their 12 scientists?</p> <p>13 A With which?</p> <p>14 Q That the risk is very low.</p> <p>15 A Let's read the sentence 16 where they say that. Then I can respond 17 to you.</p> <p>18 Q In the prior FDA cite, it 19 says, "The risk associated with abruptly 20 discontinuing the use of these important 21 medicines far outweighs the low risk that 22 our scientists estimate to be associated 23 with medication until the patient's 24 doctor or pharmacist provides a safe 25 replacement or a different treatment</p>

<p>1 option."</p> <p>2        That's one.</p> <p>3    A    Okay. Well, there, what</p> <p>4 they're saying is they're talking about a</p> <p>5 period of a couple of days. They're</p> <p>6 talking about until the medication can be</p> <p>7 replaced with a clean one. So, yeah, you</p> <p>8 know, I don't necessarily agree or</p> <p>9 disagree that three extra days of</p> <p>10 Valsartan is -- I think actually, it does</p> <p>11 confirm some significant risk. I mean I</p> <p>12 wouldn't take three of those pills right</p> <p>13 now. But if I was at high risk of having</p> <p>14 a heart attack or if I stopped abruptly,</p> <p>15 I would be forced to take them.</p> <p>16    Q    Where does it say three</p> <p>17 days?</p> <p>18    A    Well, it says until the</p> <p>19 patient's doctor or pharmacist provides a</p> <p>20 safe replacement. So I mean I would</p> <p>21 assume that people would be going about</p> <p>22 that expeditiously, rather than taking</p> <p>23 contaminated medicines.</p> <p>24    Q    Yes.</p> <p>25        You interjected three. I</p>	<p>Page 274</p> <p>1 talking about 20,000, even up to 76,000.</p> <p>2 And that's only of what was tested. So</p> <p>3 these people were taking wildly above the</p> <p>4 acceptable levels, perhaps more than any</p> <p>5 people have ever taken before and over</p> <p>6 certain periods of years.</p> <p>7    Q    But, again, you are not</p> <p>8 disagreeing with that statement I</p> <p>9 described; correct?</p> <p>10   A    That statement pertains to</p> <p>11 acceptable levels, which are under</p> <p>12 96 nanograms, which I don't specifically</p> <p>13 disagree with.</p> <p>14   Q    You don't disagree with the</p> <p>15 Bullet Point No. 4 that I just read to</p> <p>16 you there; correct?</p> <p>17        MR. SLATER: Objection. You</p> <p>18 can answer.</p> <p>19   A    I think I've just answered</p> <p>20 it.</p> <p>21   Q    Well, I just want to be</p> <p>22 clear because at the end, I want to make</p> <p>23 sure -- you don't disagree with this</p> <p>24 Bullet Point 4; correct?</p> <p>25   A    I don't disagree with that.</p>
<p>1 just want to make it clear. Three was</p> <p>2 your add; right?</p> <p>3    A    Yes.</p> <p>4    Q    And if we go back to the</p> <p>5 prior article in the FDA because that had</p> <p>6 other information, I think it was 17, you</p> <p>7 asked whether you disagreed with the FDA</p> <p>8 and the scientists on this, and the</p> <p>9 fourth bullet on the page, we talked</p> <p>10 about where it says, "Nitrosamine</p> <p>11 impurities may increase the risk of</p> <p>12 cancer if people are exposed to them</p> <p>13 above acceptable levels and over long</p> <p>14 period of times, but a person taking a</p> <p>15 drug that contains nitrosamines at or</p> <p>16 below the acceptable daily intake limits</p> <p>17 every day for 70 years is not expected to</p> <p>18 have an increased risk of cancer."</p> <p>19        Are you going to disagree</p> <p>20 with that statement?</p> <p>21    A    No. I think I've already</p> <p>22 said I don't have any real basis to</p> <p>23 disagree with that statement. But the</p> <p>24 contaminated Valsartan didn't have less</p> <p>25 than 96 nanograms per pill. I mean we're</p>	<p>Page 275</p> <p>Page 277</p> <p>1    Q    I have one other --</p> <p>2        MR. SLATER: Last question.</p> <p>3        MS. COHEN: Oh, stop.</p> <p>4        MR. SLATER: She's like one</p> <p>5 other question.</p> <p>6    Q    So, again, Doctor, why don't</p> <p>7 we pull this out. This is Dr. Chodosh's</p> <p>8 reports since we talked about it. And I</p> <p>9 want to make sure you can look at it if</p> <p>10 you want to. It cites to a reference,</p> <p>11 but it was in book form. So I didn't</p> <p>12 have enough time to get it. So that's</p> <p>13 why I'll just mark it and let you look at</p> <p>14 it.</p> <p>15        MS. COHEN: We'll give you a</p> <p>16 copy, Adam, if you want.</p> <p>17        MR. SLATER: Yes. I'm just</p> <p>18 seeing. I thought I might have it</p> <p>19 here.</p> <p>20        MS. COHEN: We got it for</p> <p>21 you.</p> <p>22        MR. SLATER: I didn't bring</p> <p>23 it.</p> <p>24        MS. COHEN: We'll mark this</p> <p>25 as Exhibit 19.</p>

<p style="text-align: right;">Page 278</p> <p>1       (The above-referred-to 2   document was marked as Exhibit 19 for 3   identification, as of this date.)</p> <p>4   Q   I know you haven't seen the 5   report. And, again, the reason I'm not 6   showing you this cite is not because I'm 7   holding it back, but because it was in 8   book form. And we don't have it yet.</p> <p>9           The page 124 -- I'm sorry. 10   Page 30, paragraph 124, are you there?</p> <p>11   A   Yes.</p> <p>12   MR. SLATER: I'm sorry, 13   Lori. You said page 30?</p> <p>14   MS. COHEN: Page 30, Cite 15   124.</p> <p>16   Q   So it talks about the 17   American Conference of Governmental 18   Industrial Hygienists.</p> <p>19   Have you read that?</p> <p>20   A   No.</p> <p>21   Q   You haven't seen that, I 22   take it?</p> <p>23   A   Never heard of that.</p> <p>24   Q   And it says, "Has classified 25   carcinogenicity of NDMA as Group A3 which</p>	<p style="text-align: right;">Page 280</p> <p>1 did show people who were exposed to NDMA 2 through the workplace.</p> <p>3   Q   What was the date on that 4 one?</p> <p>5   A   I don't know.</p> <p>6           MR. SLATER: It's referenced 7   38.</p> <p>8   A   2019.</p> <p>9   Q   Yes. This is 2019 too.</p> <p>10   A   Probably didn't have it.</p> <p>11   Q   But fair enough. I don't 12 have it with me.</p> <p>13           So I just want to see if 14 you've seen it, and the answer's no?</p> <p>15   A   Yes.</p> <p>16           (The above-referred-to 17   document was marked as Exhibit 20 for 18   identification, as of this date.)</p> <p>19   Q   Exhibit 20, this is February 20   2021 guidelines that came out by the FDA.</p> <p>21   I don't think you cited for that.</p> <p>22           Have you seen this one?</p> <p>23   A   Yeah, I did. I have seen 24   this. I think it's one of my 25   supplemental reliances.</p>
<p style="text-align: right;">Page 279</p> <p>1 denotes a confirmed animal carcinogen 2 with unknown relevance to humans."</p> <p>3           Have you heard that 4 classification?</p> <p>5   A    Nope.</p> <p>6   Q   It says, "Specifically, the 7 A3 designation indicates that 'the agent 8 is carcinogenic in experimental animals 9 at a relatively high dose, by route(s) of 10 administration, at site(s), or histologic 11 type(s), or by mechanism(s), that may not 12 be relevant to worker exposure.</p> <p>13 Available epidemiologic studies do not 14 confirm an increased risk of cancer in 15 exposed humans."</p> <p>16           Not aware of that study?</p> <p>17           MR. SLATER: Study?</p> <p>18   Q    Of that?</p> <p>19   A    It's basically impossible 20 for me to react to this without knowing 21 more about, A, this group of people, and, 22 B, when they published what they 23 published. It seems like they're looking 24 at worker exposure. I don't know if this 25 came out before the Hidajat study which</p>	<p style="text-align: right;">Page 281</p> <p>1   Q   We'll obviously check. But 2 the reason I want to bring this up is I 3 think you said earlier that the 96 4 nanograms were interim levels?</p> <p>5   A    Yes.</p> <p>6   Q    And here we have on page 10, 7 this has a section called, A, Acceptable 8 Intake Limits. It says, "The FDA 9 recommends the following several intake 10 (AI) 31 limits for nitrosamine 11 impurities."</p> <p>12           So this is moved from 13 interim to being part of this guidance 14 document; correct?</p> <p>15           MR. SLATER: Objection.</p> <p>16           Lack of foundation.</p> <p>17   Q    If you know.</p> <p>18   A    I need a minute to re-review 19 it.</p> <p>20           MR. SLATER: I can just tell 21 you -- do you want to know why I'm 22 objecting? I don't know if this is 23 only geared to Valsartan. So I just 24 want to make sure that the question 25 doesn't suggest that. I'm not saying</p>

<p>1 it does or it doesn't. But if it 2 does, I'm just preserving my 3 objection.</p> <p>4 A Okay. It looks like they 5 left the word "interim" out of this.</p> <p>6 Q On one of the supplemental 7 lists, you did cite to this one; right?</p> <p>8 A Yeah. I've looked at this 9 before. I'm pretty sure.</p> <p>10 Q It's on the first 11 supplemental list we got from Mr. Geddis 12 48 hours ago or thereabouts. So we've 13 confirmed that. You could put that 14 aside.</p> <p>15 A Okay.</p> <p>16 Q Keep things moving.</p> <p>17 Now, this quote that you 18 have on page 4 of your report, the old 19 adage, "the dose makes the poison," is 20 that a phrase you've used before?</p> <p>21 A Sure.</p> <p>22 Q It's not new to this report?</p> <p>23 A New to me?</p> <p>24 Q Yes.</p> <p>25 A No. I'm familiar with this</p>	<p>Page 282</p> <p>1 occurred, the testing and all that? 2 MS. COHEN: Right.</p> <p>3 Q That's not -- even though 4 you referenced reading the reports, that 5 was just for specific kind of markers or 6 information?</p> <p>7 MR. SLATER: Objection. You 8 can answer.</p> <p>9 Q Again, you cited to 10 depositions, but you're not here to give 11 any comments about on how the company 12 handled things?</p> <p>13 MR. SLATER: He's not giving 14 any liability opinions against Teva 15 at this stage of the litigation or 16 against any manufacturers at this 17 stage. I think we agreed to that.</p> <p>18 Q You were citing to them, but 19 not getting into the details of that?</p> <p>20 A Whatever statements I made, 21 whatever context I cited to is what I 22 would say about it.</p> <p>23 Q This is another press 24 release.</p> <p>25 (The above-referred-to</p>
<p>1 phrase.</p> <p>2 Q But have you ever said it 3 before?</p> <p>4 A Probably. I don't 5 specifically recall saying it.</p> <p>6 Q Have you ever written it 7 before?</p> <p>8 A Not that I recall.</p> <p>9 Q Do you know whether it's 10 dated or cited in any other expert 11 report?</p> <p>12 A It's sort of a cliche in 13 medicine. It certainly could be in many 14 reports. I don't know.</p> <p>15 Q I think I know the answer to 16 this. I just wanted to make sure.</p> <p>17 You cite to in your report I 18 think three different employees of Teva, 19 my client in this case. And you're 20 obviously not giving any opinions about 21 sort of how the company did things.</p> <p>22 That's outside of your purview for 23 purposes of this deposition; correct?</p> <p>24 MR. SLATER: You're talking 25 about like how the nitrosamines</p>	<p>Page 283</p> <p>1 document was marked as Exhibit 21 for 2 identification, as of this date.)</p> <p>3 Q I want to see if you've seen 4 this one, Exhibit 21.</p> <p>5 Have you seen this one 6 before?</p> <p>7 A Certainly.</p> <p>8 Q This is the one that has -- 9 I think this is part of your materials, 10 the laboratory analysis chart?</p> <p>11 A Yes.</p> <p>12 Q Which I think you inserted 13 in your report at some point?</p> <p>14 A I'm sure I cited it. But I 15 don't think I inserted it.</p> <p>16 Q And the FDA in this press 17 release, again looking at the estimated 18 risk on page 1, this is their statement. 19 "Laboratory Analysis of Valsartan 20 Products" is what it says at the top. 21 And this is where they talk about the LOD 22 or limit of detection. We've seen that.</p> <p>23 A Yup.</p> <p>24 Q And it says in the next 25 paragraph, "The FDA expects the actual</p>

<p style="text-align: right;">Page 286</p> <p>1 cancer risk to most consumers to be lower 2 than our estimate."</p> <p>3 And you don't have any 4 reason to disagree with that; correct?</p> <p>5 MR. SLATER: Objection. You 6 can answer.</p> <p>7 A Let me just find the exact 8 statement that you're referring to.</p> <p>9 Q Sure. It's the third 10 paragraph.</p> <p>11 A Well, I don't know that I 12 entirely agree with that statement.</p> <p>13 Q You just don't know, one way 14 or another?</p> <p>15 A Well, FDA didn't disclose 16 how they did their calculation. But EMA 17 did a similar calculation. And they did 18 disclose the methodology. And what they 19 did is they extrapolated TD50, tumor dose 20 50, for animals based on the mean value 21 of nitrosamines of NDMA that they found 22 in their analysis.</p> <p>23 So the mean, means that half 24 the people have more -- or half the 25 measurements are higher, and half the</p>	<p style="text-align: right;">Page 288</p> <p>1 MR. SLATER: Objection. You 2 can answer.</p> <p>3 A Look, the FDA is usually 4 right. But they're not always right. No 5 agency is always right. So I don't 6 likely say or flippantly say I disagree. 7 But I think that this is one of the 8 instances in which they could be wrong. 9 Based on the data that I see, 10 particularly some of the already 11 published data, I think that there are 12 going to be more cancers than that. 13 Q Could be wrong, but you 14 can't say that within a reasonable degree 15 of medical certainty; true?</p> <p>16 A Well, it's an estimate. So 17 I'm opining basically about an opinion at 18 this point.</p> <p>19 Q You didn't do any study 20 yourself; correct?</p> <p>21 A No.</p> <p>22 Q And you're referring to some 23 of the --</p> <p>24 A I assume you mean I didn't 25 do a study where I personally calculated</p>
<p style="text-align: right;">Page 287</p> <p>1 measurements are lower. So, you know, 2 for any individual person, you don't have 3 a 1 in 8,000 risk. The risk is going to 4 be different for each person. This is 5 maybe a big-picture calculation. But 6 it's not applicable to an individual 7 person.</p> <p>8 Q What it says is the FDA 9 estimates that if 8,000 people took the 10 highest Valsartan dose, 320 milligrams 11 containing NDMA from recall batches daily 12 for four years, and maybe one additional 13 case of cancer over the lifetime of the 14 8,000 patients?</p> <p>15 A Right. That's an estimate. 16 Since the numbers are fairly similar to 17 EMA, I'm going to presume they probably 18 used the same methodology which is based 19 on the mean. And the mean, as I said, 20 half the people had a higher dose than 21 the mean.</p> <p>22 Q So are you taking the 23 position that you disagree with the FDA 24 and what they say here about the cancer 25 risk being lower than their estimate?</p>	<p style="text-align: right;">Page 289</p> <p>1 a dose response?</p> <p>2 Q Yes.</p> <p>3 A I did not do that.</p> <p>4 Q You didn't take the data 5 that the EMA and the FDA used and run any 6 calculations yourself?</p> <p>7 A Right. I didn't make my own 8 model based on their data. But I did 9 read the published literature, 10 specifically with respect to cancer 11 potency, including what we're already 12 seeing in the use of Valsartan. And I 13 drew a conclusion which I think this is 14 going to be worse than what FDA states 15 here.</p> <p>16 Q And that's totally 17 speculative on your part, isn't it, 18 Doctor?</p> <p>19 MR. SLATER: Objection. You 20 can answer.</p> <p>21 A Sure. Well, it's not 22 speculative. I'm basing it on Peer 23 Review published literature.</p> <p>24 Q Which literature?</p> <p>25 A Well, Al-Kindi showed an</p>

<p style="text-align: right;">Page 290</p> <p>1 effect; Gomm showed liver cancer effect. 2 Q Any others? 3 A I believe it's Pottegård. 4 Q You cite to three in your 5 report. You don't cite them necessarily 6 by name. But you cite three articles on 7 pages 25 -- 8 A So Pottegård was showing -- 9 didn't reach the statistical significance 10 yet. But there are trends towards 11 increased cancer, including 46 percent 12 increased risk of colorectal cancer and 13 80 percent risk of uterine cancer. 14 Q Did not reach statistical 15 significance; true? 16 A That is true. But those 17 trends are very disturbing. And I think, 18 you know, this is a very short latency 19 period. So give this more time to 20 develop. And these numbers could be -- 21 well, let's say they can get a lot worse. 22 Q And it's funny. We're going 23 to go through your part about latency 24 periods with the Valsartan studies. 25 You say it's a very short</p>	<p style="text-align: right;">Page 292</p> <p>1 "false," are you citing to Al-Kindi, Gomm 2 and Pottegård or are you citing to the 3 dietary studies? 4 A Well, I'm not -- I excluded 5 my answer just now to not include dietary 6 studies because you asked specifically 7 about Valsartan. But the ones that show 8 statistically significant potency for 9 cancer from Valsartan itself are Al-Kindi 10 and Gomm. 11 Q Now, you haven't seen -- 12 because you've only been given 13 Dr. Catenacci. You haven't seen what any 14 of the defense experts -- and I'll tell 15 you there are nine in total -- had to say 16 about your report and your opinions and 17 your assessment of the articles; correct? 18 A Correct. 19 Q You haven't seen any 20 summaries of them from plaintiffs' 21 counsel? 22 A No. 23 Q Has Mr. Slater or his team 24 told you what they had to say about any 25 of these articles in your use of them?</p>
<p style="text-align: right;">Page 291</p> <p>1 latency period, you said? 2 A Yes. With respect to 3 cancer, short latency. 4 Q You do say in your report, 5 "Some common carcinogenic exposures can 6 take decades, 30 years or more"; right? 7 A Some, yeah; some less. 8 Q That would not be short, 9 would it? 10 A 30 years? 11 Q Yes. 12 A No. 13 Q We'll circle back to that in 14 your bell curve discussion a little bit. 15 I just want to finish this part. 16 A Sure. 17 Q Now, none of the cites of 18 the literature that you established in 19 your report establishes an increased risk 20 of cancer from the oral ingestion of 21 NDMA -- NDMA containing Valsartan 22 products in terms of human 23 carcinogenicity; true? 24 A False. 25 Q And, again, when you say</p>	<p style="text-align: right;">Page 293</p> <p>1 A He mentioned a few 2 particular points. 3 Q What points did he mention? 4 A It's hard for me to remember 5 specifically what we discussed. 6 Q And I'll jump through some 7 of this. So we may get it to anyway. 8 I'm curious. 9 When Mr. Slater was talking 10 to you in one of your recent meetings or 11 discussions, did he say let me tell you 12 what so-and-so has to say about you? 13 They each had sections about you. Did he 14 tell you that? 15 A He made a couple of comments 16 about it. Again, I'm having a hard time 17 recalling exactly what was said. 18 MR. SLATER: Just to be 19 clear, we're going to be able to ask 20 all your experts about all the 21 discussions with counsel; right? 22 It's open season; right? I didn't 23 object. But I assume no defense 24 lawyer is going to object when we 25 question the defense experts about</p>

<p>1 discussions with counsel.</p> <p>2 MS. COHEN: I'm not agreeing 3 to that.</p> <p>4 MR. SLATER: Then I object. 5 Move on to another subject.</p> <p>6 Q I'm asking you, are you 7 aware of what the defense experts have 8 said about you?</p> <p>9 MS. COHEN: That's fair.</p> <p>10 MR. SLATER: It's a 11 different question.</p> <p>12 Q Are you aware of what they 13 said about you?</p> <p>14 A As a professional scenario, 15 I hope they haven't said too much about 16 me.</p> <p>17 Q I'm sorry.</p> <p>18 A As far as my report?</p> <p>19 Q Yes.</p> <p>20 MR. SLATER: They said some 21 stuff about your musical taste.</p> <p>22 A You know, as I said, Mr. 23 Slater made a couple of comments about --</p> <p>24 MR. SLATER: Don't talk 25 about what I said.</p>	<p>Page 294</p> <p>1 heard before.</p> <p>2 Q In your report, you did the 3 opposite; correct?</p> <p>4 MR. SLATER: Objection. You 5 can answer.</p> <p>6 A Well, I mean in some 7 situations, that statement that you made 8 is a little bit misleading; you know, if 9 I want to know if jumping out of the 10 ninth floor is harmful, should I start 11 with the null hypothesis or could I use a 12 little bit of common sense?</p> <p>13 Q Just to be clear, on page 14 11 -- I think we covered some of this 15 before -- you actually do the opposite of 16 the null hypothesis study?</p> <p>17 MR. SLATER: Objection. You 18 can answer.</p> <p>19 A In the very specific case of 20 someone being exposed to a significant 21 amount of a carcinogenic compound and 22 then developing a cancer, I would start 23 with a very high index of suspicion that 24 that carcinogenic compound contributed to 25 their cancer.</p>
<p>1 THE WITNESS: Okay.</p> <p>2 MR. SLATER: They don't want 3 to have an even playing field on 4 that. So we're not going to go 5 there.</p> <p>6 A Nothing jumps out as a major 7 thing.</p> <p>8 Q You said Al-Kindi and Gomm 9 are the ones you cited to?</p> <p>10 MR. SLATER: Objection. I 11 object to the characterization.</p> <p>12 A Yes.</p> <p>13 Q What's a scientific method?</p> <p>14 A What is a scientific method?</p> <p>15 Q Yes.</p> <p>16 A Hypothesis-driven, 17 evidence-based research, testing, testing 18 replication.</p> <p>19 Q Have you ever heard that the 20 scientific method or heard or read 21 scientific method is that the null 22 hypothesis should be true, that there's 23 no association of causation unless it's 24 proven otherwise?</p> <p>25 A That is a statement I've</p>	<p>Page 295</p> <p>1 Q But that's understood. 2 But that's not what you did; 3 you didn't start with a high degree of 4 suspicion or whatever your quote was; you 5 started that the assumption that exposure 6 to a human carcinogen contributed to this 7 carcinogenesis; you did the opposite of 8 the null hypothesis? Wouldn't you agree 9 with that?</p> <p>10 MR. SLATER: Objection. You 11 can answer.</p> <p>12 A Again, in this specific 13 context, I don't think that one needs to 14 start with the null hypothesis by the 15 same reasoning that, you know -- well, I 16 gave an example.</p> <p>17 Q Do you agree that what you 18 did in your report with your assumptions 19 as you noted, page 11 and into page 12, 20 you did the opposite of a null 21 hypothesis?</p> <p>22 MR. SLATER: Objection. You 23 can answer.</p> <p>24 A I think it's unfair to 25 characterize the whole report based on</p>

<p>1 that statement.</p> <p>2 Q I'm going to then -- I won't</p> <p>3 state the entire report. I'm going to</p> <p>4 say, you're dealing with the key</p> <p>5 question, the core question that we</p> <p>6 discussed earlier.</p> <p>7 You did the opposite of a</p> <p>8 null hypothesis; true?</p> <p>9 MR. SLATER: Objection. You</p> <p>10 can answer.</p> <p>11 A No. I don't think the</p> <p>12 things that are dealt in this report</p> <p>13 really impact -- let me read the</p> <p>14 statement again, please.</p> <p>15 Q Okay. Page 11.</p> <p>16 A So in that statement, it's</p> <p>17 talking about any patient, talking about</p> <p>18 a particular patient. I'm not talking</p> <p>19 about a general approach or methodology</p> <p>20 to reviewing scientific literature. So,</p> <p>21 no, I wouldn't agree with your</p> <p>22 characterization.</p> <p>23 Q The crucial part is it</p> <p>24 starts with the assumption that exposure</p> <p>25 to a human carcinogen contributed to</p>	<p>Page 298</p> <p>1 So, first of all, you talk</p> <p>2 about the three studies.</p> <p>3 Again, you agree these are</p> <p>4 Gomm, Pottegård and Al-Kindi; right?</p> <p>5 A Those are the three that are</p> <p>6 being referred here.</p> <p>7 Q When you talk about the</p> <p>8 Danish study, that's Pottegård; is that</p> <p>9 right? German study's Gomm, and the</p> <p>10 study looking at adverse events reported</p> <p>11 to the FDA is Al-Kindi? I just want to</p> <p>12 make sure we're on the same page.</p> <p>13 A The FDA one is certainly</p> <p>14 Al-Kindi, I believe it's true; Pottegård</p> <p>15 is Danish; and Gomm is German; Al-Kindi,</p> <p>16 American.</p> <p>17 Q First of all, you say in the</p> <p>18 very beginning, you talk about the</p> <p>19 potential latency period is extremely</p> <p>20 short in each study.</p> <p>21 A Yes.</p> <p>22 Q And you talk about the</p> <p>23 latency period -- precise latency period</p> <p>24 is still being studied, and the maximum</p> <p>25 follow-up in the study is six years, a</p>
<p>1 carcinogenesis in the patient cancer</p> <p>2 unless there is convincing evidence to</p> <p>3 the contrary.</p> <p>4 Is it your position that is</p> <p>5 not the opposite of the null hypothesis?</p> <p>6 MR. SLATER: Objection. You</p> <p>7 can answer.</p> <p>8 A Sure. That's dealing with</p> <p>9 looking at a particular patient. It's</p> <p>10 not dealing with taking the literature as</p> <p>11 a whole.</p> <p>12 Q Does that say anything about</p> <p>13 a patient in there?</p> <p>14 A Yes.</p> <p>15 Q Any patient?</p> <p>16 A That is the part about a</p> <p>17 patient and the previous sentence.</p> <p>18 Therefore, for any patient. Both make</p> <p>19 specific reference to specific patients.</p> <p>20 Q Page 24 is where you get</p> <p>21 into the discussion of the Valsartan</p> <p>22 articles that we mentioned a little while</p> <p>23 ago. So just so you know where I'm</p> <p>24 going. And we'll pull them out here in</p> <p>25 just a few minutes.</p>	<p>Page 299</p> <p>1 pretty short latency period in most</p> <p>2 cancers; right?</p> <p>3 A Yes.</p> <p>4 Q What you're saying there is</p> <p>5 that the studies are too short but the</p> <p>6 latency periods are long; right?</p> <p>7 A You're asking me if I think</p> <p>8 biologically, the latency periods for</p> <p>9 cancer due to NDMA are long?</p> <p>10 Q Yes.</p> <p>11 A Well, as I say here, it's</p> <p>12 still being studied. So I think it's</p> <p>13 unclear at the moment.</p> <p>14 Q So to be clear, to a</p> <p>15 reasonable degree of medical certainty,</p> <p>16 you cannot offer an opinion as to the</p> <p>17 latency periods involved in these cancers</p> <p>18 that are at issue in this case?</p> <p>19 MR. SLATER: Objection. You</p> <p>20 can answer.</p> <p>21 A There is some data to this</p> <p>22 effect. You could look at Hidajat which</p> <p>23 did have a latency period. I believe it</p> <p>24 was seven years, immediate latency period</p> <p>25 of seven years, Hidajat. So there is</p>

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<p>1 some evidentiary basis to offer an 2 opinion in that regard. 3 Q I understand that. 4 And there are certainly 5 experts who have offered opinions on 6 that, the latency period. 7 I'm saying, you do not have 8 an opinion as to a reasonable degree of 9 medical certainty to the latency period 10 because as you say here, it's still being 11 studied; is that right? 12 MR. SLATER: Objection. You 13 can answer again. 14 A It's still being studied. 15 And we don't know exactly. But looking 16 at the preliminary report, the first 17 pieces of data, such as Hidajat, I think 18 that was seven years, was a good study, 19 big study. 20 Q You haven't offered any 21 opinions specifically about the latency 22 period; is that right? 23 A I haven't offered a specific 24 opinion on latency. 25 Q Let's pull out Gomm.</p>	<p>Page 302</p> <p>1 A Well, when one is reviewing 2 scientific or medical literature, 3 different studies can get different 4 weights for various reasons, quality, 5 strength of association, many different 6 factors come into it. Pottegård did not 7 achieve, did not reach statistical 8 significance which is why I can't put a 9 lot of weight on it. 10 But there were trends 11 towards increased cancer in Pottegård. 12 So it is alarming. The other -- 13 Pottegård has two really big problems. 14 One is that they -- their study group was 15 ZHP -- sorry -- ZHP Valsartan users. And 16 their control group was users of other 17 Valsartan products. So they don't say 18 who their white list was. 19 And since this study was 20 done, you know, we now know many 21 different manufacturers had NDMA 22 contaminated Valsartan. So it's quite 23 possible that Valsartan use across the 24 board, both in the patient and the 25 subject's end controls, was artificially</p>
<p>1 (The above-referred-to 2 document was marked as Exhibit 22 for 3 identification, as of this date.) 4 (The above-referred-to 5 document was marked as Exhibit 23 for 6 identification, as of this date.) 7 (The above-referred-to 8 document was marked as Exhibit 24 for 9 identification, as of this date.) 10 MS. COHEN: Why don't we 11 pull out all of them: Pottegård, 12 Gomm and Al-Kindi. 22 will be Gomm; 13 23 will be Pottegård; 24, Al-Kindi. 14 Q So let's look at Pottegård 15 first. 16 A Okay. 17 Q And I notice when I asked 18 you to tell me which articles quoted your 19 opinion that there was some Valsartan 20 studies that showed increased risk of 21 cancer. You did not include Pottegård. 22 You said Al-Kindi and Gomm. So I know 23 this one is not part of that. But you do 24 cite to it in your report. So I want to 25 just cover it briefly; is that correct?</p>	<p>Page 303</p> <p>1 high because of Valsartan use; in fact, 2 Al-Kindi supported that hypothesis. 3 Q Let me try to go through 4 this quickly and just cover a couple of 5 points. 6 One is, you agree that this 7 did not show a statistically significant 8 increase in cancer risk from NDMA 9 contaminated Valsartan products; correct? 10 A Pottegård? 11 Q Yes. 12 A I agree. 13 Q And I think what it says 14 here is on page -- three pages I think 15 under results, I'll let you catch up 16 there, it just says, "Overall, exposure 17 to potentially (probably or possibly) 18 NDMA contaminated Valsartan products 19 showed no association with cancer 20 compared with exposure to Valsartan 21 products unlikely to be contaminated with 22 NDMA and no evidence of a dose-response 23 relation." 24 That's what you're pointing 25 to; right?</p>

1           MR. SLATER: Objection. You 2 can answer. 3       A Right. It says that. But 4 they don't tell us which manufacturers 5 were in which group. 6       Q But we agree that this could 7 not be used to support the position that 8 there's some increased risk; correct? 9           MR. SLATER: Objection. 10      A Yeah. I think that that 11 would be overstating my position on that. 12 I think, as I said, when you're reviewing 13 medical and scientific literature, you 14 can put various amounts of weight on 15 various studies based on a number of 16 factors. The fact that it didn't reach 17 statistical significance certainly limits 18 its utility. But it doesn't completely 19 trivialize it. 20       As I said, there were trends 21 towards increased cancer for colorectal 22 and uterine cancer. And that in and of 23 itself I think is quite interesting 24 because those cancers are seen most 25 commonly -- well, those are the most	Page 306	1 excluding individuals with Lynch 2 Syndrome? 3       A Well, I criticized this 4 article for excluding patients who had a 5 previous diagnosis of cancer. And I 6 mentioned that the cancers, which were 7 showing trends towards increased 8 incidents, are the cancers that are most 9 commonly seen in patients with Lynch 10 Syndrome. Lynch Syndrome was what I was 11 just referring to when I said some 12 patients have deficient machinery to 13 clean up their DNA. 14       Q But you don't know of any 15 studies that actually establish that NDMA 16 or NDEA causes or accelerates cancer 17 growth with Lynch Syndrome? You can't 18 cite a study; right? 19           MR. SLATER: Objection. You 20 can answer. 21      A Well, I know the mechanism 22 by which NDMA -- NDMA causes mutation in 23 cells. And it's precisely the kind of 24 thing that you would want the enzymes of 25 Lynch Syndrome to face. So I would say	Page 308
1 common cancers in people who have 2 deficient DNA cleanup machinery. 3       Q So this cites to IARC for 4 one. You see that in here? 5       A Pottegård? 6       Q Yes. 7       Pottegård cites IARC? 8       MR. SLATER: Where are you? 9       What page? The first page right 10 there? 11       MS. COHEN: No. It's a 12 little bit further. It's the section 13 on biological rationale. It's three 14 from the back. These don't have page 15 numbers. 16       MR. SLATER: I saw it on the 17 front page. 18       MS. COHEN: Maybe it's on 19 the front page too. 20       Q They're obviously 21 referenced, the IARC; right? 22       A Yes. They're referenced, 23 the IARC. 24       Q One of the things I think 25 you criticized the study for was	Page 307	1 patients, if they have a deficiency in 2 those cleanup -- in the cleanup machinery 3 would be at very high risk from in-dose 4 to digesting dosages of NDMA as described 5 in Valsartan. 6       Q Is there any study that you 7 can cite to for that? I know you said 8 you know what kind of study there would 9 be. Is there any kind of study we should 10 be aware of? 11       MR. SLATER: Objection. You 12 can answer. 13      A There's no study, yet, of 14 Valsartan use in Lynch Syndrome patients 15 in cancer outcomes. 16       Q So let's move to Gomm. 17      A Sure. 18       Q Which we marked. 19       That's one of the ones that 20 you cite to as being supportive of your 21 answer to the big question in the report 22 about risk of cancer. This is one of the 23 two; right? 24       A Well, I really -- so the big 25 question was not answered on the basis of	Page 309

<p>1 any two studies. The big question was 2 answered on the basis of pretty much 3 everything that I've referenced here. So 4 the dietary studies, the animal studies, 5 the WHO, the IARC. And these studies 6 played a part, Gomm and Al-Kindi, as did 7 everything else, including the negative 8 studies.</p> <p>9 Q In terms of actual studies, 10 articles and studies for human carcinogen 11 increase, the only two studies you cite 12 here are Gomm and Al-Kindi; true?</p> <p>13 MR. SLATER: Objection. You 14 can answer.</p> <p>15 A No. There are quite a few 16 studies that I reference that show 17 potency with respect to cancer for NDMA.</p> <p>18 Q You're talking about dietary 19 studies?</p> <p>20 A Yes.</p> <p>21 Q Putting those aside for this 22 moment, these are the two studies: Gomm 23 and Al-Kindi; true?</p> <p>24 MR. SLATER: Objection. You 25 could answer.</p>	<p>Page 310</p> <p>1 suggest that the consumption of 2 NDMA-contaminated Valsartan is associated 3 with a slightly increased risk of hepatic 4 cancer; no association was found with the 5 risk of cancer overall."</p> <p>6 MR. SLATER: Objection.</p> <p>7 A That's what it says.</p> <p>8 MR. SLATER: Objection.</p> <p>9 Q And you read the article, 10 and you know that's not what it says, but 11 that's what it found; right?</p> <p>12 A In a short time frame, yeah. 13 I think that studies like this in ten 14 years might look dramatically different. 15 But for now, they found already an 16 increased incident of liver cancer which 17 is a deadly and horrible disease and no 18 other causative associations thus far.</p> <p>19 Q Did you learn in your 20 preparation today what other experts had 21 to say about the Gomm article and the 22 failings of it?</p> <p>23 A No.</p> <p>24 Q And I would say that what it 25 says in the conclusion, which comes</p>
<p>1 A These are the two studies 2 that specifically deal with the 3 contaminated Valsartan pills and 4 association with cancer.</p> <p>5 Q And looking at this Gomm 6 study, I know you've read it, of course; 7 right?</p> <p>8 A I've read it.</p> <p>9 Q You probably read this 10 multiple times since it's one of the two 11 that you cite to for that particular 12 issue?</p> <p>13 MR. SLATER: Objection.</p> <p>14 Lack of foundation.</p> <p>15 Q Did you read this recently?</p> <p>16 A Relatively recently.</p> <p>17 Q Last night?</p> <p>18 A No.</p> <p>19 Q Today?</p> <p>20 A No.</p> <p>21 Q Sometime in the last week?</p> <p>22 A Maybe. One to two weeks.</p> <p>23 Q Conclusion of the study -- 24 I'm kind of a highlights person -- 25 conclusion on page 1 is, "These findings</p>	<p>Page 311</p> <p>1 obviously at the end of this 35762, it 2 says --</p> <p>3 MR. SLATER: You're talking 4 about the conclusion?</p> <p>5 MS. COHEN: Yes.</p> <p>6 MR. SLATER: Let me just get 7 there.</p> <p>8 MS. COHEN: It's before 361.</p> <p>9 MR. SLATER: Okay. I'm 10 there.</p> <p>11 Q It says, "We detected a 12 small, yet statistically significant 13 increase in the risk for liver cancer 14 with the use of NDMA-contaminated 15 Valsartan while no association was found 16 for overall cancer risk or other examined 17 single cancer outcomes" similar to what 18 it says in the front part.</p> <p>19 Then it says, "However, the 20 present study can only state the 21 existence of a statistical association. 22 Causality cannot be inferred"; right?</p> <p>23 MR. SLATER: Objection. You 24 can answer.</p> <p>25 Q That's what it said; right?</p>

<p style="text-align: right;">Page 314</p> <p>1 A It did. And it goes on to 2 say, "Long-term effects of regular use of 3 potentially NDMA contaminated Valsartan 4 for more than three years could not be 5 evaluated because of the currently still 6 relatively short follow-up time."</p> <p>7 Q Let me ask you a few 8 additional questions about Gomm. 9 A Sure.</p> <p>10 Q While found a statistically 11 significant association, there was no 12 dose-dependent effect observed; correct?</p> <p>13 A Is there a specific line, 14 part that you're referring to where it 15 says --</p> <p>16 Q No. I'm just asking if you 17 know that.</p> <p>18 A I don't recall if they 19 commented on that.</p> <p>20 Q So this is 358.</p> <p>21 A Okay.</p> <p>22 Q And on the right-hand column 23 about three quarters of the way down, it 24 says, "However, no dose-dependent effect 25 on the risk of liver cancer was found for</p>	<p style="text-align: right;">Page 316</p> <p>1 types of cancer one type at a time? Are 2 you aware of that?</p> <p>3 A Where are you reading that?</p> <p>4 Q From my expert's report. 5 just being honest.</p> <p>6 A Can you give it to me again?</p> <p>7 Q If you don't know that, it's 8 fine.</p> <p>9 A We could move on. I didn't 10 quite get the question. But we could 11 move on, if you want, or we could go 12 through it again.</p> <p>13 Q No. I want to keep moving. 14 The last part was, it did 15 not correct for multiple testing.</p> <p>16 A Multiple testing.</p> <p>17 Q Testing for an association 18 for multiple types of cancer.</p> <p>19 A I don't think I totally 20 understand what the expert was saying 21 with that comment.</p> <p>22 Q I'm sure he can handle it 23 far better than I can.</p> <p>24 And, again, it ends with, 25 "Causality cannot be inferred" in the</p>
<p style="text-align: right;">Page 315</p> <p>1 higher exposure to potentially any 2 NDMA-contaminated Valsartan."</p> <p>3 Do you see that?</p> <p>4 MR. SLATER: Sorry. What 5 page did you say?</p> <p>6 MS. COHEN: 358.</p> <p>7 Q You see that?</p> <p>8 A Okay. I see that.</p> <p>9 Q And the study did not 10 control for other risk factors for liver 11 cancer.</p> <p>12 Do you agree with that?</p> <p>13 A Well, right above where you 14 just highlighted, it says, "The 15 association with liver cancer remains 16 stable after basic adjustment for age and 17 gender and also after additional 18 adjustment for hepatitis and other liver 19 diseases."</p> <p>20 So I think that it did 21 certainly make adjustments for hepatitis 22 and liver diseases.</p> <p>23 Q Also, this study did not 24 correct for multiple testing, i.e., 25 testing for an association for multiple</p>	<p style="text-align: right;">Page 317</p> <p>1 conclusion part.</p> <p>2 You saw that; right?</p> <p>3 A Yeah.</p> <p>4 Q Now, Al-Kindi is our last 5 one that I want to go to. And we marked 6 this. You should have it over there.</p> <p>7 Two pages in total; right?</p> <p>8 A Yeah.</p> <p>9 Q This is the one that the 10 FDA -- adverse event reporting that you 11 mentioned in your report?</p> <p>12 A Yeah.</p> <p>13 Q And this is the one -- tell 14 me if I'm wrong about this -- that we 15 talked about before where this came after 16 the recall -- and I may get objected 17 to -- but I think you said this had sort 18 of the impact of the press and PR and the 19 recall leading to kind of a spike; is 20 this what you were talking about?</p> <p>21 A Yeah. So I think what this 22 article was really kind of saying -- and 23 I'm going to make the case of it very 24 believed, actually -- but what they were 25 saying is, wow, if you look at the chart</p>

<p style="text-align: right;">Page 318</p> <p>1 on page 2, they're saying, oh my God,      2 look at how many tumors were reported as      3 adverse events after the recall. And so,      4 you know, these people taking these      5 medicines must have panicked. And anyone      6 who got cancer blamed it on their drug.      7 And, okay, fine, certainly, people who      8 see this in the news and recently gotten      9 a diagnosis of cancer may make that      10 conclusion, not necessarily an error.      11 They could be right. But what to me      12 really jumped off the page, if you look      13 on the first page of this, the fourth      14 paragraph, reporting odds ratio for      15 neoplasm adverse event, increased from      16 1.7, and then it gives paren 1.3 to 2.1,      17 pre-recall to 7.1 post recall. So that's      18 saying, wow, it went from 1.7 to 7.1.      19 And that's a lot. But what that 1.7 is,      20 is a pre-recall number showing the odds      21 of reporting a tumor as an adverse event      22 from Valsartan compared to other ARBs was      23 1.7, meaning 170 percent other ARBs or a      24 70 percent increase to other ARBs. So      25 there's no psychological explanation for</p>	<p style="text-align: right;">Page 320</p> <p>1 event was 70 percent higher for Valsartan      2 users, compared to consumers of other      3 angiotensin receptor blockers, even      4 before the NDMA contamination was      5 announced.</p> <p>6 Where in the study do you      7 derive this statistic from?</p> <p>8 A Well, I just explained it.</p> <p>9 If you look at the fourth paragraph on      10 page 1 of this study, reporting odds      11 ratio for neoplasm AEs, adverse events,      12 increased from 1.7. So 1.7 means that      13 those users, users of Valsartan had a      14 70 percent higher risk of reporting a      15 neoplasm adverse event pre-recall.</p> <p>16 Q Right.</p> <p>17 But --</p> <p>18 A 1.7 is the statistic. Then      19 it shows the range there, the confidence      20 interval of 1.3 to 2.2.</p> <p>21 Q But you go from neoplasm to      22 cancer; you're conflating those two      23 words, aren't you?</p> <p>24 A Well, they're all tumors.</p> <p>25 And I'm sure most of them are cancerous</p>
<p style="text-align: right;">Page 319</p> <p>1 why that number should be 1.7 pre-recall.      2 And just to put a fine point      3 on it, it indicates that Valsartan use      4 was associated with tumor development or      5 at least the reporting of tumors before      6 the recall.</p> <p>7 Q So, first of all, you talk      8 in your report on page 26 about this      9 article, and you say a massive spike in      10 neoplasms reported adverse events; right?</p> <p>11 A What page?</p> <p>12 Q Page 26 in your report.</p> <p>13 A Yes.</p> <p>14 Q Neoplasms are not cancer?</p> <p>15 A Many of them are. In old      16 people, most of them are. But there are      17 some that are not neoplasms. That's      18 true.</p> <p>19 Q They're not all malignant?</p> <p>20 A Not everyone is malignant.      21 But they're tumors. They are tumors.      22 Not every neoplasm is a tumor.</p> <p>23 Q What's particularly striking      24 about the article was the calculated risk      25 of reporting a neoplasm as an adverse</p>	<p style="text-align: right;">Page 321</p> <p>1 because these are old people taking this      2 drug.</p> <p>3 Q But you don't know that, do      4 you? Do you know that all of those      5 neoplasms are cancerous?</p> <p>6 A I didn't say all of them are      7 cancerous. I said a lot of them are      8 cancerous.</p> <p>9 Q You're speculating on that,      10 aren't you?</p> <p>11 MR. SLATER: Objection. You      12 can answer.</p> <p>13 Q You said most of them are      14 cancerous.</p> <p>15 A Most neoplasms in people of      16 the age group taking Valsartan are      17 cancerous. Some are benign tumors. I'm      18 sure there are some benign tumors in      19 there. But my statement is accurate.</p> <p>20 Q You don't think you're      21 speculating when you say that?</p> <p>22 A I'm basing it on well-known      23 epidemiology that most neoplasms in      24 people in their 60s and 70s are going to      25 be malignant.</p>

<p>1 Q There's a section in your 2 report, Ranitidine Studies, page 28. The 3 Yoon study also found -- I could pull it 4 out. I'm sure you read it recently; 5 right? Yoon. It's the only one you cite 6 to in the section.</p> <p>7 A I don't think it's the only 8 study that I cite to in the section. I 9 mean I did read this study. If we're 10 going to talk about it in detail, I would 11 like to see it.</p> <p>12 Q I'm just going to ask you 13 one question right now.</p> <p>14 Are you aware that study 15 found no association between cancer and 16 ingestion in nitrosamines?</p> <p>17 A I'm aware that this study 18 found no association between the 19 nitrosamine levels in Ranitidine and 20 cancer so far. Ranitidine levels are 21 much lower than what's been reported for 22 Valsartan. And, again, this suffers from 23 the same problems as Gomm and Pottegård 24 which is that it may need more time.</p> <p>25 Q So no one should rely on</p>	<p style="text-align: right;">Page 322</p> <p>1 Q And then we'll get where we 2 get to.</p> <p>3 So can you name for us as 4 many human carcinogens that you could 5 name?</p> <p>6 A Oh, boy. Okay. Cigarette 7 smoke, smokeless tobacco.</p> <p>8 MR. SLATER: While you're 9 doing that, objection to the 10 question. But you can continue to 11 answer.</p> <p>12 A Radiation, asbestos, 13 nitrosamines, Human Papilloma Virus, 14 Epstein Barr Virus, Human T-cell Lymphoma 15 Virus, Clonorchis, Chinese Liver Fluke, 16 Schistosoma, Reflux. Well, that's not -- 17 that's not an exogenous one. Hepatitis B 18 Virus, Hepatitis C Virus, alcohol, 19 certain asbestosiform minerals, such as 20 tremolite. There are probably more. I 21 can keep thinking about them, if you'd 22 like.</p> <p>23 Q I'm going to ask you a 24 follow-up question.</p> <p>25 A Okay.</p>
<p>1 them with any degree of certainty, is 2 what you're saying?</p> <p>3 MR. SLATER: Objection. You 4 can answer.</p> <p>5 A They're one piece of the 6 puzzle. We had to go through all of the 7 research to take the disparate data 8 points and synthesize them into an 9 opinion.</p> <p>10 I think I might like another 11 break soon.</p> <p>12 Q Why don't we do it now.</p> <p>13 THE VIDEOGRAPHER: We are 14 off the record. The time is 15 4:35 p.m. Eastern Time.</p> <p>16 (A short recess was taken.)</p> <p>17 THE VIDEOGRAPHER: We are 18 back on the record. The time is 19 4:57 p.m. Eastern Time.</p> <p>20 Q So, Doctor, I'm going to 21 just shift gears a little bit, move away 22 from the literature and your report for a 23 little while and ask you some general 24 questions that I have.</p> <p>25 A Sure.</p>	<p style="text-align: right;">Page 323</p> <p>1 Q Do you consider there to be 2 a universal carcinogen?</p> <p>3 MR. SLATER: Objection. You 4 can answer.</p> <p>5 A What do you mean by that?</p> <p>6 Q That each type of these 7 potential carcinogen has the same 8 reaction.</p> <p>9 A You mean across species?</p> <p>10 Q Well, and in people in terms 11 of type of cancer they cause.</p> <p>12 A Can you ask the question a 13 little differently? It's a little hard 14 for me to get.</p> <p>15 Q Well, for the various 16 cancers that you named before, what types 17 of human cancers do they cause? Do they 18 cause the same types or different ones?</p> <p>19 A For the carcinogens that I 20 mentioned before?</p> <p>21 Q Yes.</p> <p>22 A I mean they -- each can 23 cause various types of cancer. And 24 there's a concept perhaps that -- they 25 each can cause various types of cancer.</p>

<p style="text-align: right;">Page 326</p> <p>1 Well, some would only cause one type of 2 cancer. Hepatitis B or Hepatitis C, for 3 example, causes liver cancer.</p> <p>4 Q On page 18 of your report -- 5 I know I was getting away from your 6 report -- I want to go back to this one 7 point. You said on page 18 -- it says, 8 "However, it's worth noting that once a 9 carcinogen has entered the bloodstream, 10 it's likely that it can cause cancers in 11 nearly any organ."</p> <p>12 What's the basis for saying 13 that?</p> <p>14 A The basis for saying that is 15 that once a carcinogen is in the blood, 16 it can be pumped to any part of the body. 17 And so many of the carcinogens that we 18 mentioned before are not bloodborne.</p> <p>19 Q And you'd agree that the 20 presence of a carcinogen, whether it's 21 NDMA or something else, in the 22 bloodstream by itself, that fact does not 23 make NDMA carcinogenic? The fact that 24 NDMA is in the bloodstream, that doesn't 25 make it carcinogenic?</p>	<p style="text-align: right;">Page 328</p> <p>1 universal, meaning any single organ in 2 any single person, something can cause 3 cancer. A carcinogen can cause cancer. 4 I can't think of an example right now. 5 Ionizing radiation, maybe.</p> <p>6 Q Back to page 18 of your 7 report, you go on to say, "It will be 8 difficult for one to scientifically 9 exclude the potential for a bloodborne 10 carcinogen to cause cancer in any organ 11 to a reasonable degree of medical 12 certainty."</p> <p>13 Again, you have no cite 14 there; correct?</p> <p>15 A There's no cite, right.</p> <p>16 Q And you have no cite to give 17 us for that statement, do you?</p> <p>18 MR. SLATER: Objection. You 19 can answer.</p> <p>20 A It's an opinion based on my 21 knowledge of biology and pathobiology. 22 Probably, it could have been said better 23 by adding "without prospective data."</p> <p>24 Q It's your opinion there's no 25 prospective data to support that; is that</p>
<p style="text-align: right;">Page 327</p> <p>1 A It's the DNA damage that 2 makes it carcinogenic.</p> <p>3 Q Well, it still has to be 4 metabolized, doesn't it?</p> <p>5 A Yes. And then it causes DNA 6 damage.</p> <p>7 Q On the universal carcinogen, 8 are you asking me to re-ask the question?</p> <p>9 A Yes.</p> <p>10 Q Is there any carcinogen that 11 equally can cause all types of cancer?</p> <p>12 A That's a concept I haven't 13 considered before. So there's a concept 14 in medicine called the multi-specificity, 15 which I think would apply to this 16 discussion, whereas if we say something 17 is specific, that seems to exclude other 18 avenues.</p> <p>19 But take, for example, like 20 cigarette smoking, it is a multi-specific 21 carcinogenic. It can cause lung cancer. 22 Obviously, it can cause head and neck 23 cancers. It can cause bladder cancer. 24 So it's multi-specific. And there are a 25 lot of multi-specific carcinogens,</p>	<p style="text-align: right;">Page 329</p> <p>1 right?</p> <p>2 MR. SLATER: Objection. You 3 can answer.</p> <p>4 A That's not exactly what I'm 5 saying, no. I'm saying that carcinogens 6 that enter the bloodstream like NDMA and 7 its metabolites could potentially cause 8 any cancer. Now, it may be true that 9 over time, we'll learn it's more likely 10 to cause Cancer Y, X and Z than A, B, C. 11 But that data doesn't exist yet.</p> <p>12 Q And can you point to any 13 studies cited in your report that is 14 determined that the NDMA will reach the 15 bloodstream after oral ingestion for up 16 to 20 micrograms of NDMA?</p> <p>17 A Yes.</p> <p>18 Q Which ones?</p> <p>19 A Well, of course, it's 20 well-known. It's a scientific consensus 21 that NDMA does get into the bloodstream. 22 That is not a contentious issue. I'll 23 try to find the specific reference now. 24 As far as I'm aware, there's not a shred 25 of scientific argument against that</p>

<p>1 proposition.</p> <p>2 Q Well, it doesn't mean it's</p> <p>3 carcinogenic just because it's in the</p> <p>4 bloodstream; right?</p> <p>5 MR. SLATER: Objection. You</p> <p>6 can answer.</p> <p>7 A Yeah. I mean there are two</p> <p>8 different questions. If you're asking,</p> <p>9 is NDMA -- does NDMA get into the</p> <p>10 bloodstream, I think it's completely</p> <p>11 uncontroversial. I can probably find it</p> <p>12 in the WHO article from 2002, a</p> <p>13 reference, if you need it. But it's</p> <p>14 well-known there's scientific consensus.</p> <p>15 As to whether or not it's a</p> <p>16 carcinogen being in the blood does not in</p> <p>17 and of itself make it a carcinogen, if</p> <p>18 that was your question.</p> <p>19 Q Yes. That's fair.</p> <p>20 And you don't have any</p> <p>21 specific citation, as you said, for those</p> <p>22 two sentences or one sentence -- no --</p> <p>23 two sentences on page 18?</p> <p>24 A Those two bolded sentences?</p> <p>25 Q Yes.</p>	<p>Page 330</p> <p>1 were you referring to a specific</p> <p>2 plaintiff in this litigation or was</p> <p>3 it a general statement?</p> <p>4 THE WITNESS: General</p> <p>5 statement.</p> <p>6 Q And even on the general</p> <p>7 aspect of it, you haven't -- and, again,</p> <p>8 as you said, let me find the exact</p> <p>9 pages -- I don't want to forget to ask --</p> <p>10 page 33.</p> <p>11 You said, "Anyone who</p> <p>12 actually develops cancer as a result of</p> <p>13 being exposed to contaminated-Valsartan</p> <p>14 with NDMA and NDEA has been harmed."</p> <p>15 This is a general statement</p> <p>16 you're making; if someone gets cancer,</p> <p>17 you consider that a harm; right?</p> <p>18 MR. SLATER: Objection. You</p> <p>19 can answer.</p> <p>20 MS. COHEN: I'm taking it</p> <p>21 one sentence at a time.</p> <p>22 A Yes. Certainly, anyone who</p> <p>23 develops a cancer as a result of being</p> <p>24 exposed to contaminated Valsartan with</p> <p>25 nitrosamines has been harmed.</p>
<p>1 A There's not a citation to</p> <p>2 that. Those are professional opinions</p> <p>3 based on my knowledge and experience.</p> <p>4 Q And one thing I meant to ask</p> <p>5 about, in your report, you talk sort of</p> <p>6 at the end about injuries and harm and</p> <p>7 what people experience.</p> <p>8 Again, you're not offering</p> <p>9 those opinions today at this point in</p> <p>10 this litigation because you're not</p> <p>11 getting into any case-specific issues or</p> <p>12 assessing people, what they've</p> <p>13 experienced; is that correct?</p> <p>14 MR. SLATER: Objection. You</p> <p>15 can answer. Do you mean he's not</p> <p>16 offering an opinion on any specific</p> <p>17 patient at this time?</p> <p>18 MS. COHEN: Yes.</p> <p>19 A Yeah. I mean --</p> <p>20 Q I'll start with that.</p> <p>21 A Yeah. I mean as a human, I</p> <p>22 feel for all the people who took this</p> <p>23 drug.</p> <p>24 MR. SLATER: Her question</p> <p>25 is, when you made that statement,</p>	<p>Page 331</p> <p>1 Q But in terms of how they've</p> <p>2 been harmed, what long-term risks they</p> <p>3 have, what exactly they have suffered,</p> <p>4 again, that's not anything you're able to</p> <p>5 comment on today to a reasonable degree</p> <p>6 of medical certainty?</p> <p>7 MR. SLATER: Objection. You</p> <p>8 can answer.</p> <p>9 A I find the question a little</p> <p>10 bit overly broad. If, again, we're</p> <p>11 talking about any particular person, I'm</p> <p>12 not commenting today on any particular</p> <p>13 people with any particular disease.</p> <p>14 Q Right.</p> <p>15 And the next piece of it --</p> <p>16 because I don't want to leave here and</p> <p>17 regret not asking this.</p> <p>18 The next piece of it, even</p> <p>19 though you've given this general</p> <p>20 statement -- well, let me ask this.</p> <p>21 You would offer the opinion</p> <p>22 that anybody who's developed cancer has</p> <p>23 suffered harm; right?</p> <p>24 A That would again be overly</p> <p>25 broad. Anyone who develops cancer in</p>

<p>1 what context?</p> <p>2 Q In any capacity.</p> <p>3 You obviously said you feel</p> <p>4 terrible for anyone who develops cancer;</p> <p>5 correct?</p> <p>6 A I do.</p> <p>7 Q And, again, it's a</p> <p>8 generalization that you feel like if</p> <p>9 somebody develops cancer from some</p> <p>10 exogenous source, they've been harmed;</p> <p>11 correct?</p> <p>12 A Yeah. I mean the specific</p> <p>13 question you just asked, if people</p> <p>14 developed cancer from an exogenous</p> <p>15 source, then, yes, definitely.</p> <p>16 Q But to go any further, in</p> <p>17 other words, in terms of what oncologic</p> <p>18 risk, what future harms someone might</p> <p>19 have, what they will experience, that</p> <p>20 again, you're not able to offer to a</p> <p>21 reasonable degree of medical certainty</p> <p>22 here because you haven't studied those</p> <p>23 issues?</p> <p>24 MR. SLATER: Objection. You</p> <p>25 can answer.</p>	<p style="text-align: right;">Page 334</p> <p>1 instances, they show a certain amount of</p> <p>2 NDMAAs associated with a certain amount of</p> <p>3 increased cancer.</p> <p>4 So I am directionally aware</p> <p>5 of what the risks may be. But for this</p> <p>6 particular question -- the Valsartan</p> <p>7 question is going to be different</p> <p>8 depending on which medications the</p> <p>9 patient was taking.</p> <p>10 Q The amount of it?</p> <p>11 A Yeah.</p> <p>12 Q Time frame of it?</p> <p>13 A All of that.</p> <p>14 Q And confounding factors?</p> <p>15 A All those factors come into</p> <p>16 play.</p> <p>17 Q Multifactorial, it could be</p> <p>18 Valsartan, it could be combined with</p> <p>19 something else; so, in other words,</p> <p>20 sitting here today, whatever day it is</p> <p>21 today -- I don't even know -- 2021 --</p> <p>22 what's the date today? Friday the 13th,</p> <p>23 you can't offer any opinion to a</p> <p>24 reasonable degree of medical certainty as</p> <p>25 to the risk of future harm or the</p>
<p>1 A Well, for some of these</p> <p>2 products, the degree of contamination is</p> <p>3 unprecedented in human history. As far</p> <p>4 as I know, there's never been a time</p> <p>5 where people might have consumed</p> <p>6 50,000 nanograms per day of NDMA.</p> <p>7 So, you know, for me to give</p> <p>8 an exact -- an exact risk rate, I don't</p> <p>9 think anyone can really do it right now.</p> <p>10 You could make models. You could make</p> <p>11 guesses. But we don't know the exact</p> <p>12 risk. And especially if you're going to</p> <p>13 talk about a particular person, then we</p> <p>14 have to look at the whole case.</p> <p>15 Q You have not assessed, for</p> <p>16 example, the oncologic risk, the risk</p> <p>17 that they would at some point in their</p> <p>18 life develop cancer? You have not done a</p> <p>19 modeling or assessment of that; correct?</p> <p>20 MR. SLATER: Objection. You</p> <p>21 can answer.</p> <p>22 A I haven't done my own</p> <p>23 mathematical models. I have read through</p> <p>24 the studies, including the dietary</p> <p>25 studies, which do show -- both in many</p>	<p style="text-align: right;">Page 335</p> <p>1 increased risk? You haven't studied all</p> <p>2 that; correct?</p> <p>3 MR. SLATER: Objection. You</p> <p>4 can answer.</p> <p>5 A I don't agree with that</p> <p>6 characterization at all. I think -- so</p> <p>7 there's a degree of precision that I</p> <p>8 cannot provide because we basically don't</p> <p>9 have an evidentiary basis for what</p> <p>10 happens if you take multiple thousands of</p> <p>11 milligrams of this substance.</p> <p>12 But I have looked at the</p> <p>13 evidence that exists. And that concludes</p> <p>14 dietary studies which show rather</p> <p>15 significant potency for NDMA causing</p> <p>16 cancer. So based on the dietary studies,</p> <p>17 as well as animal studies, if you're</p> <p>18 asking me if I can say to a reasonable</p> <p>19 degree of medical certainty whether these</p> <p>20 people have been harmed or not, I</p> <p>21 absolutely believe they've been harmed.</p> <p>22 Q What you can't say to a</p> <p>23 reasonable degree of medical certainty is</p> <p>24 what the increased risk is they will at</p> <p>25 some point in their lives develop cancer?</p>

<p style="text-align: right;">Page 338</p> <p>1 That's not something you can offer today; 2 right?</p> <p>3 MR. SLATER: Objection. You 4 can answer.</p> <p>5 A Like a precise percentage?</p> <p>6 Q Yes, percentage anything, 7 right.</p> <p>8 A I could give -- it could be 9 answered in a couple of ways. One way is 10 we've never seen this much NDMA 11 administered to people before. At the 12 lower levels, I think that you could 13 definitely make an analogy to the dietary 14 studies.</p> <p>15 Q So, again, I'll just go back 16 to what I said before.</p> <p>17 You haven't talked to any of 18 these people; correct?</p> <p>19 A If I can clarify my previous 20 answer, you know, the dietary studies, 21 some of them show about like a -- we can 22 go to my report here. There are some 23 that show 40, 60 or 100 percent increase 24 risk for high dietary consumers of NDMA. 25 And so those dietary</p>	<p style="text-align: right;">Page 340</p> <p>1 is the specificity? Where are the 2 percentages, the numbers?</p> <p>3 A There's a difference between 4 precision and specificity. I don't put 5 any precise statements in here. But I do 6 think the statements are specific to 7 people -- I mean the statements read as 8 it reads. But I don't consider them 9 particularly non-specific. I mean they 10 are sort of a closing statement.</p> <p>11 But I think it's absolutely 12 true that if you are a person in 2012, 13 you had hypertension, you had X percent 14 chance you were going to get cancer in 15 your life. Me, everyone here has 16 some percent chance they're going to get 17 cancer. The people who took these 18 medicines have a more likelihood of 19 getting cancer.</p> <p>20 Q But you cannot in any way 21 give us a citation as to what the 22 increase is; correct?</p> <p>23 A I think I just explained 24 that for people at the lower end of the 25 spectrum, we can go to the dietary</p>
<p style="text-align: right;">Page 339</p> <p>1 studies, the high consumers of NDMA are 2 consistent with the very low end of the 3 spectrum for contaminated-Valsartan 4 pills. So I think in those instances, I 5 could give you a relatively reasonable 6 estimate of increased risk, the people 7 who are taking 25,000 nanograms, 50,000 8 and 76,000 nanograms. I have no idea. 9 No human has ever been subjected to that, 10 to the best of my knowledge, but a lot.</p> <p>11 Q Here's my issue.</p> <p>12 Page 33, you throw in at the 13 end this paragraph about harm, an 14 unreasonable oncologic risk, having 15 increased the risk; there's not a single 16 citation there -- correct? -- in that 17 paragraph.</p> <p>18 A That's right.</p> <p>19 Q You also do not express any 20 opinion, other than these generalities, 21 about the degree of risk, percentage of 22 risk? There's no specificity here. You 23 agree with that?</p> <p>24 A No.</p> <p>25 Q What do you mean no? Where</p>	<p style="text-align: right;">Page 341</p> <p>1 literature where the numbers are 2 relatively analogous. And with that, we 3 probably could put together a pretty 4 reasonable model.</p> <p>5 Q But you haven't done that 6 here, have you?</p> <p>7 MR. SLATER: Objection. You 8 can answer.</p> <p>9 Q Is there -- look at this 10 paragraph. Is there any number in here? 11 Is there any model in here? Anything?</p> <p>12 MR. SLATER: You're talking 13 about on this page?</p> <p>14 MS. COHEN: Yes.</p> <p>15 Q This is your chance to do 16 it.</p> <p>17 Is there any number here?</p> <p>18 MR. SLATER: Objection. You 19 can answer the question.</p> <p>20 A I disagree that this is the 21 place I would have to do that. I spoke 22 in great detail in this report about the 23 increased cancer rates for dietary 24 studies. And we can look.</p> <p>25 And for everyone where I had</p>

1 an amount of ingestion, I included that, 2 that data. So we can look at the 3 specific drug products and the specific 4 levels of contamination. And then we can 5 say, okay, if this is analogous to Study 6 X and this is the increased amount of 7 cancer for some of them as I said, I mean 8 you could never ethically give someone 9 tens of thousands of nanograms of NDMA. 10 Q Do you understand that if 11 you didn't do some analysis or some 12 calculation or some modeling put in your 13 report, it's not in the report. 14 I'm asking you, did you do a 15 modeling or calculation for harm or a 16 reasonable oncologic risk anywhere? 17 MR. SLATER: Objection. You 18 can answer. 19 Q Did you do it? 20 A I didn't do a calculation, 21 no. I relied on calculations in the Peer 22 Review literature. 23 Q In the dietary studies you 24 mentioned? 25 A Yeah.	Page 342  1 Q Sitting here today, 2021, do 2 we know all the reasons why people 3 develop cancer? 4 A All the reasons, no. We 5 know a lot of the reasons. But I 6 couldn't say all. 7 Q Do individuals who are not 8 exposed to environmental carcinogens 9 develop cancer? 10 A Definitely. 11 Q Do individuals -- 12 MR. SLATER: One second. 13 Objection to the form. I just didn't 14 want to step on your answer. 15 Q Do individuals who do have 16 an inherent predisposition of cancer 17 still develop cancer? 18 A Some, sure. Many. 19 Q Can observational 20 epidemiologic studies prove causation? 21 Let me retract that and look 22 at what you said on page 22. I'm going 23 to withdraw that question for now. 24 Would you agree that DNA 25 damage commonly occurs in the cells of
Page 343  1 Q And you didn't try to take 2 those and extrapolate in this -- because 3 this is the only paragraph where you talk 4 about harm -- come up with any type of 5 calculations for this litigation? 6 MR. SLATER: Objection. 7 Mischaracterization of the report. 8 You can answer again. 9 A So I didn't personally take 10 any of the original data and model to do 11 some sort of risk assessment model. 12 Q And none of the other 13 experts who are part of the plaintiffs' 14 expert team did so; correct? 15 MR. SLATER: Objection. 16 A I have no idea. 17 Q You haven't seen any of 18 those? 19 A I have not seen any of them. 20 Q You haven't been told about 21 any modeling they've done? 22 A No. 23 Q Or any increased risk 24 analysis? 25 A No.	Page 345  1 our bodies as a result of endogenous 2 processes or is it always external 3 exogenous factors? 4 MR. SLATER: Objection. You 5 can answer. 6 A It's both. Certainly both. 7 Q And you agree -- I think you 8 said this earlier. 9 You agreed earlier that 10 association does not mean causation? You 11 agreed with that earlier? 12 A Right. 13 Q And you also agree that risk 14 factors, not all risk factors are not 15 causes? 16 A What's that? 17 Q All risk factors for cancer 18 are not causes of cancer. Do you agree 19 with that? 20 MR. SLATER: Objection. You 21 can answer. 22 A All risk factors for cancer 23 are not causes for cancer. As a general 24 supposition, I would agree with that. 25 Q How long does it typically

<p>1 take to develop cancer starting from a 2 normal cell without mutations until the 3 time a cancer is clinically diagnosed or 4 diagnoseable?</p> <p>5 MR. SLATER: Objection. You 6 can answer.</p> <p>7 A Without knowing the specific 8 cancers in question, it's almost 9 impossible to answer that. There are 10 some that can take ten years or more. 11 There are some that can be detected on 12 the order of weeks. So it's a really 13 broad range.</p> <p>14 Q There was one part of your 15 report where you were talking about 16 polyps. I'm trying to see where that is. 17 I'm going to ask you a 18 question, how long does it take for a 19 polyp in a colon to turn into invasive 20 colon cancer?</p> <p>21 MR. SLATER: Objection. You 22 can answer.</p> <p>23 A From the first day that it's 24 a polyp to the day that it's a cancer, 25 you know, there's not an exact timeline.</p>	<p>Page 346</p> <p>1 there's a mutation in the KRAS oncogene. 2 At that point, it's still not usually 3 invasive carcinoma. But the typical 4 third hit would be a mutation in the TP53 5 tumor suppressor gene. And by the time 6 that happens, there's a very good chance 7 of the polyp becoming an invasive cancer. 8 Often, you'll have a final hit, which is 9 the TPC4 gene detected in pancreas 10 cancer, although in this case, we're 11 talking about it in relation to 12 colorectal cancer. So the reason a polyp 13 becomes an invasive cancer is because it 14 requires additional somatic genetic 15 mutation as I just described.</p> <p>16 Q Is it your opinion to a 17 reasonable degree of medical certainty 18 that exposure to even a single molecule 19 of a carcinogen can be sufficient to 20 cause cancer?</p> <p>21 A I would think that that's a 22 very extreme statement.</p> <p>23 Q So you would not express 24 that opinion?</p> <p>25 A As a general rule, that</p>
<p>1 But ten years or more in most cases with 2 outliers.</p> <p>3 Q So the latency period is 4 long; correct?</p> <p>5 A For colon?</p> <p>6 Q Yes.</p> <p>7 A Yes. But latency period is 8 not a term I would use in that context.</p> <p>9 Q What would you use?</p> <p>10 A Just the rate of progression 11 is slow until the point it's cancer, then 12 it's fast, slowly, and then all at once.</p> <p>13 Q If a polyp becomes an 14 invasive cancer, can you tell what caused 15 it to become invasive?</p> <p>16 A Yeah. I mean this is -- 17 that question gets at really the basis of 18 colorectal carcinogenesis. And 19 typically, when you have a polyp, you see 20 the first mutation in a gene called APC, 21 adenomatous polyposis coli, causes the 22 polyp. As it progresses, the polyp 23 requires additional genetic defects. So 24 typically -- and, again, there are 25 outliers. But typically, the next one,</p>	<p>Page 347</p> <p>1 would not seem terribly plausible to me. 2 There may be some substances that are so 3 potently carcinogenic. I don't know what 4 plutonium might do if put in the wrong 5 place. But as a general rule, I find 6 that statement to be -- I don't find that 7 to be one molecule being terribly 8 convincing.</p> <p>9 Q As a general rule, you would 10 agree, I'm sure, that common carcinogenic 11 exposures could take decades to cause 12 cancer; right?</p> <p>13 MR. SLATER: Objection. You 14 can answer.</p> <p>15 A Sure. Some, definitely.</p> <p>16 Q How many packs of cigarettes 17 does it take to cause lung cancer in a 18 cigarette smoker?</p> <p>19 MR. SLATER: Objection. You 20 can answer.</p> <p>21 A A number.</p> <p>22 Q What's the shortest period 23 of time it takes to develop cancer, 24 starting from the normal cell without 25 mutations in key genes until the time a</p>

<p>1 cancer is clinically diagnosed?</p> <p>2 MR. SLATER: Objection. You</p> <p>3 can answer.</p> <p>4 A I believe you asked that</p> <p>5 exact question. I'm virtually sure. The</p> <p>6 answer is the same. It doesn't matter.</p> <p>7 The answer is I can't answer that</p> <p>8 question without knowing the specific</p> <p>9 cancer in question. There are some that</p> <p>10 could take decades to become clinically</p> <p>11 apparent. And there are others that can</p> <p>12 become clinically apparent within a</p> <p>13 matter of weeks or even days in some</p> <p>14 instances. So it's an overly broad</p> <p>15 question. Weeks to decades, days to</p> <p>16 decades is my answer.</p> <p>17 Q I take it that you do not</p> <p>18 have an opinion to a reasonable degree of</p> <p>19 medical certainty as to a typical period</p> <p>20 of time it takes for NDMA or NDEA to</p> <p>21 cause cancer?</p> <p>22 MR. SLATER: Objection. You</p> <p>23 can answer.</p> <p>24 Q Given the limitations of the</p> <p>25 studies we talked about earlier.</p>	<p>Page 350</p> <p>1 A Straif is the next paper</p> <p>2 referenced in my report.</p> <p>3 Q Since you've referred to</p> <p>4 this Hidajat several times, this is the</p> <p>5 one about the lifetime exposure rubber</p> <p>6 dust fumes and nitrosamines and cancer</p> <p>7 mortality and a cohort of British rubber</p> <p>8 workers?</p> <p>9 A That is the study, yes.</p> <p>10 Q The study followed rubber</p> <p>11 factor workers; correct?</p> <p>12 A It did.</p> <p>13 Q And rubber workers were</p> <p>14 exposed to a variety of substances,</p> <p>15 including aromatic amines, which are</p> <p>16 known to be associated with an increased</p> <p>17 risk of bladder cancer?</p> <p>18 A A number of substances,</p> <p>19 right.</p> <p>20 Q This study did not take into</p> <p>21 account in any way, smoking or factor</p> <p>22 that in or out; correct?</p> <p>23 MR. SLATER: Objection. You</p> <p>24 can answer.</p> <p>25 A So what the study did that</p>
<p>1 A Well, the issue of</p> <p>2 latency -- and, you know, we got to that</p> <p>3 a little bit earlier. Maybe I didn't</p> <p>4 make myself entirely clear. We have some</p> <p>5 studies that get at latency, including</p> <p>6 Hidajat, which was I believe seven years,</p> <p>7 was the immediate latency period, which</p> <p>8 implies that for some, it's longer, ten</p> <p>9 years or more; some, it's less, three</p> <p>10 years, an order of three years.</p> <p>11 And I think that Gomm, for</p> <p>12 example, has three years of follow-up.</p> <p>13 And it shows an increased risk of liver</p> <p>14 cancer. So the low end of the spectrum</p> <p>15 is probably a couple of years; the high</p> <p>16 end is still being defined.</p> <p>17 Q While you mentioned the</p> <p>18 Hidajat, let's pull out that one which is</p> <p>19 I think cited on page 17.</p> <p>20 (The above-referred-to</p> <p>21 document was marked as Exhibit 25 for</p> <p>22 identification, as of this date.)</p> <p>23 (The above-referred-to</p> <p>24 document was marked as Exhibit 26 for</p> <p>25 identification, as of this date.)</p>	<p>Page 351</p> <p>1 was very important, was they were able to</p> <p>2 estimate the exposures of the substances.</p> <p>3 So aromatic amines are one. NDMA are</p> <p>4 another. So they did a careful analysis</p> <p>5 in that regard.</p> <p>6 As to how they dealt with</p> <p>7 the issue of smoking, my guess is that a</p> <p>8 ton of people that worked in the British</p> <p>9 rubber industries, starting in 1967,</p> <p>10 smoked. But I don't have a recollection</p> <p>11 off the top of my head of how they dealt</p> <p>12 with that in this paper. I'm happy to</p> <p>13 take some time to go through it if you'd</p> <p>14 like.</p> <p>15 Q You cited this in your</p> <p>16 report; correct?</p> <p>17 MR. SLATER: Do you want him</p> <p>18 to find that and explain that to you?</p> <p>19 MS. COHEN: No. I'm going</p> <p>20 to ask the question.</p> <p>21 Q You cited this in your</p> <p>22 report --correct?-- this article?</p> <p>23 A Yes.</p> <p>24 Q On page 257, I think it's</p> <p>25 where the issue of smoking comes up. So</p>

<p>1 on the bottom of this paragraph, you can 2 certainly read through it, it ends with 3 suggesting that confounding by a smoking 4 cohort was likely not a significant 5 confounding factor.</p> <p>6 A I'm just reading through 7 that section. Okay. I've read that 8 section.</p> <p>9 Q Does that answer the 10 question about how they dealt with this 11 cohort and the smoking aspect?</p> <p>12 A Yes. They statistically 13 modeled the potential for bias from 14 smoking and concluded that it was not a 15 significant confounding factor.</p> <p>16 Q Now, this is the McElvenny. 17 It's the next article that we gave you, 18 No. 26.</p> <p>19 Q You haven't read this one, 20 have you?</p> <p>21 A Did I cite this one?</p> <p>22 Q No. I don't think so unless 23 it came in one of the supplemental 24 citations.</p> <p>25 A Have you seen this one</p>	<p style="text-align: right;">Page 354</p> <p>1 cohort. It might help you get to the 2 answer. And it even refers to the 3 predecessor.</p> <p>4 A So where is it that you're 5 finding that this same cohort is the 6 Hidajat cohort? I don't see that.</p> <p>7 Q Well, there's several 8 places. First is --</p> <p>9 MR. SLATER: Is it really?</p> <p>10 I just want to understand the 11 question. You're asking, is 12 McElvenny a subsequent article about 13 the Hidajat group?</p> <p>14 MS. COHEN: Yes. Same 15 cohort.</p> <p>16 Q So page 849, assembly of 17 study cohort, did you read that section?</p> <p>18 A Yeah.</p> <p>19 Q And then also --</p> <p>20 A But the study it references 21 to in previous analysis, Reference 6, is 22 not Hidajat.</p> <p>23 Q But look at page 854 also.</p> <p>24 A It was also published before 25 Hidajat.</p>
<p>1 anywhere?</p> <p>2 A I'm not entirely sure if I 3 did or did not. If I didn't supply it, I 4 didn't rely on that.</p> <p>5 Q So this is the same cohort 6 as Hidajat from what I can tell.</p> <p>7 A It may be or it may not be. 8 Not having been really familiar with it, 9 I can't agree to that.</p> <p>10 MR. SLATER: Do you want to 11 take your time and take a look at it 12 since you've been asked the question?</p> <p>13 THE WITNESS: Sure.</p> <p>14 Q Let me ask the question. 15 You have never seen this 16 before; right, Doctor? You've never read 17 this?</p> <p>18 MR. SLATER: Objection.</p> <p>19 Asked and answered. You can answer 20 again.</p> <p>21 A I don't have a specific 22 recollection of doing so.</p> <p>23 Q In terms of the study 24 cohort, you can look at page 849, it 25 talks about the assembly of the study</p>	<p style="text-align: right;">Page 355</p> <p>1 Q It's the same --</p> <p>2 A McElvenny.</p> <p>3 Q It's the same cohort.</p> <p>4 A Okay. I haven't seen 5 evidence of that yet. But I'll keep 6 looking.</p> <p>7 Q Let me show you this. This 8 may clarify it.</p> <p>9 Also, if you want to look at 10 page 854, it talks about it being the 11 same cohort. It talks about the 12 prospective cohort based on the consensus 13 in the industry carried out in 1967.</p> <p>14 A Page 854, you said?</p> <p>15 Q Yes.</p> <p>16 A I'm still not finding any 17 reference here that says it's the same 18 cohort as Hidajat.</p> <p>19 Q And we can deal with that 20 later. But look down here.</p> <p>21 It says on page 854, 22 "Third -- on this study -- we had no 23 information on smoking or any other 24 important risk factors such as work in 25 other industries, exposure to asbestos or</p>

1 diet. This omission could have resulted 2 in a bias in those SMRs potentially 3 affected by those risk factors. Our 4 findings will be subject to multiple 5 significance testing." 6 Do you see that part? 7 A I see that part. But I 8 don't even know what this study deals 9 with, who these patients are. That 10 statement that you read, I agree that's 11 what it says in this paper. I have no 12 idea what means or what the context is. 13 It means nothing to me at this point. 14 Q I understand. This wasn't 15 part of your reliance list. This wasn't 16 something you looked at. Let's just 17 agree on that; okay? 18 A Okay. Are we moving past 19 this? 20 Q Yes. 21 A I just want to be clear. 22 That statement that we just read in this 23 paper, as far as I understand it, has no 24 relevance to my report. 25 Q You don't believe it has any	Page 358	1 any of the other reports. And I didn't 2 look up any of the literature. 3 Q Understood. 4 A Catenacci. 5 Q So your report on page 21, 6 it says, "Amino acids in proteins are one 7 of the building blocks of nitrosamines." 8 You see that on page 21? 9 A Let me just find that. Yes. 10 I see that sentence. 11 Q And there's no cite there; 12 correct? 13 A True. 14 Q How are nitrosamines 15 produced through amino acids? 16 A So when you have a 17 nitrosamine, or formally, N-nitrosamines, 18 nitrogen group containing nitrosamines, 19 are amines which an amino acid produces 20 an amine. And a nitrosamine is attached 21 to it. Nitrites would be a common donor 22 of the nitrosamine group. So under 23 specific conditions, particularly under 24 acidic conditions, proteins or amino 25 acids and nitrosamines and other	Page 360
1 connection to Hidajat? 2 A I've never seen it before. 3 I don't know what it means, what it says 4 or who the patients are. So at this 5 point, I ascribe it no value. 6 Q Understood. 7 There's a lot of studies 8 that you didn't look at; correct? 9 MR. SLATER: Objection. Is 10 that argumentative? 11 MS. COHEN: No, not at all. 12 Q In general, you didn't 13 intend in your 33-page report to cover 14 every article that exists out there, did 15 you? 16 A I read all the ones I found 17 that seemed relevant and important. 18 Q But after the nine expert 19 reports and defense side came in, did you 20 make any effort to find out who they 21 cited to, what articles they cited and 22 try to review those? 23 MR. SLATER: Objection. You 24 can answer. 25 A Other than one, I didn't see	Page 359	1 nitrogen-containing compounds can form 2 nitrosamine. 3 Q That happens inside the 4 body; correct? 5 A Well, it can happen 6 endogenously or exogenously. It can 7 happen outside of any body. It can 8 happen in a lake. 9 Q Would you agree that fruits 10 and vegetables are a major source of 11 ingested nitrates and nitrites? 12 MR. SLATER: Objection. You 13 could answer. 14 A Different fruits and 15 different vegetables have a different 16 amount of nitrate and nitrite. Nitrate 17 is not really harmful to the best of my 18 recollection. Nitrites are. Also, there 19 are certain foods that aggregate the 20 effect of nitrites, Vitamin C-containing 21 fruit foods, which would be a lot of 22 fruits. 23 Q Speaking of fruits, would 24 you agree that food that we all consume 25 is typically composed or comprised of	Page 361

<p>1 tens of thousands of different types of 2 molecules in compounds?</p> <p>3 A Tens of thousands?</p> <p>4 MR. SLATER: Objection. You 5 can answer.</p> <p>6 A I don't have a specific 7 opinion as to how many molecules are in 8 an average -- how many different types of 9 molecules are an average.</p> <p>10 Q I want to ask you about -- 11 because we talked a lot today. And I 12 want to make sure we mark the binders 13 before we go.</p> <p>14 Your research approach when 15 you said you found most of the articles, 16 you did the searching, how did you go 17 about searching for the articles in this 18 case? What did you search?</p> <p>19 A Nitrosamine -- well, okay. 20 Let me just back up a little bit. I 21 approached this the way I would try to 22 describe the background of a scientific 23 or medical question in a research 24 article. And that would be to start with 25 typically a search of PubMed, PubMed</p>	<p>Page 362</p> <p>1 multiple occasions. I would try to come 2 up with different terms to try to capture 3 as much of the literature as I could.</p> <p>4 Q Did you share the search 5 results with counsel?</p> <p>6 A No.</p> <p>7 Q I know that the question 8 before you answered, that you were the 9 one that found most of the articles, not 10 counsel finding them for you; is that 11 fair?</p> <p>12 A Yes.</p> <p>13 Q And again, you shared them 14 with counsel?</p> <p>15 A Yes.</p> <p>16 Q The articles?</p> <p>17 A Yes.</p> <p>18 Q Your report on page 5, I 19 don't think I asked you about this. But 20 I want to make sure I cover it.</p> <p>21 The top of page 5, you 22 state, "Moreover, it's probable that 23 individuals who are predisposed to cancer 24 for any reason, genetic or environmental, 25 have an even greater likelihood of</p>
<p>1 database of Peer Review articles. And to 2 do that, I would search for key terms: 3 Nitrosamine, NDMA, dietary NDMA, NDMA 4 cancer, whatever else. I would also look 5 to statements by regulatory bodies, 6 international agencies, WHO article, 7 which we haven't had a chance to talk 8 about yet, unfortunately, WHO, IARC. And 9 that's the way I would frame -- frame a 10 discussion of a background question in a 11 scientific paper.</p> <p>12 Q So my question again was 13 just to make sure I have down what search 14 terms you used.</p> <p>15 You said nitrosamine?</p> <p>16 A NDMA, nitrosamine. I didn't 17 keep a list of what search terms I used.</p> <p>18 Q You didn't keep the 19 search --</p> <p>20 MR. SLATER: You're still 21 answering?</p> <p>22 THE WITNESS: Yes, I was.</p> <p>23 MR. SLATER: Continue.</p> <p>24 THE WITNESS: Okay.</p> <p>25 A Right. I searched on</p>	<p>Page 363</p> <p>1 developing cancer following and in part 2 as a result of ingestion of NDMA or NDEA 3 at the levels established with the 4 contaminated Valsartan."</p> <p>5 No cite there, is there?</p> <p>6 A That's my professional 7 opinion based on my review of the Peer 8 Review medical literature, my knowledge 9 of cancer biology.</p> <p>10 Q And you can't offer a cite 11 to support that, can you?</p> <p>12 MR. SLATER: Objection. You 13 can answer.</p> <p>14 A It's my professional 15 opinion, yes. I didn't pull that from a 16 different document. I included that for 17 myself, based on the Peer Review 18 literature that I reviewed, I included in 19 my report.</p> <p>20 Q Can you give us any cite 21 that stands for the proposition that 22 individuals who are predisposed to cancer 23 for any reason have a greater likelihood 24 of developing cancer following ingestion 25 of NDMA or NDEA?</p>

<p>1 A Well, it's a scientific 2 inference based on the fact that we know 3 NDMA is an alkylating -- or when it's 4 metabolized, NDMA is an alkylating agent 5 which causes methylguanine formation. 6 Methylguanine is one of the most 7 mutagenic nucleic acids known to man. 8 So if you already have a 9 problem predisposed to cancer, it's a 10 perfectly reasonable scientific inference 11 based on the mechanism of injury that 12 those people would be at increased risk. 13 Q I understand that's your 14 inference. I understand that's what 15 you're saying. 16 Is there any article 17 citation to give us that you believe 18 supports that? 19 A As we spoke about before, 20 there are different levels of evidence 21 and different weight that you could put 22 on different studies. But to get to the 23 specific -- I want to be very responsive 24 to your particular question. I would say 25 that Pottegård does provide preliminary</p> <p>1 evidence in that regard. 2 As I said, the fact that 3 Pottegård's trends -- and I admit they're 4 not significant at this point. So I'm 5 not saying it's definitely true. I'm 6 saying that there's reason to believe 7 it's true. The trends for increased 8 cancer in Pottegård work for colon cancer 9 and uterine cancer. Colon cancer and 10 uterine cancer are the two most common 11 cancers amongst patients with Lynch 12 Syndrome. 13 So I think it is -- 14 certainly when you have the mechanistic 15 evidence, and we know the mechanisms by 16 which NDMA does cause mutations, then we 17 have at least preliminary data, showing 18 that the cancers that were trending 19 towards significance in Pottegård are 20 those associated with Lynch which would 21 be a genetic predisposition syndrome to 22 cancer. I think that that supports my 23 evidence-based hypothesis here. 24 Q Well, on the -- are you 25 aware of any studies that demonstrate</p>	<p>Page 366</p> <p>1 that individuals with Lynch Syndrome have 2 an increased risk of cancer following 3 exposure to NDMA and NDEA? 4 MR. SLATER: Objection. You 5 can answer. 6 A There have not been any 7 studies to date about patients with Lynch 8 Syndrome exposed to NDMA and NDEA. 9 Q The part where we're reading 10 where you don't have a cite on the top of 11 page 5 because of your professional 12 opinion? 13 A Yeah. 14 Q I heard you say that. 15 But it's your professional 16 opinion; right? 17 A Yes. 18 Q And I think you said that's 19 your supposition, did you say? 20 A Maybe. 21 Q What genetic factors are you 22 talking about here that predispose an 23 indication of cancer? What factors are 24 you referring to? 25 A Well, there are a number</p> <p>Page 367</p> <p>1 of -- quite a few, actually, genetically 2 factors that could predispose someone to 3 cancer. The one that comes to my mind 4 most acutely in this context is -- as 5 we've discussed, Lynch Syndrome. But 6 there are any number of other cancer 7 predisposition syndromes. 8 Familial adenomatous 9 polyposis, for example, causes hundreds 10 of colon polyps. If you start ingesting 11 something that cranks up the rate of 12 mutation in those polyps, you could be in 13 similar trouble. I mean we could talk 14 about a lot of them and what would be 15 plausible hypotheses for why they would 16 put someone at an increased risk for 17 cancer. But I think the early data 18 points towards Lynch Syndrome as being 19 relevant. 20 Q You also mentioned 21 environmental factors. 22 Which ones are you referring 23 to when you said that on line 2, page 5 24 of the supposition? 25 A Well, I mean it's part and</p>
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<p>1 parcel of the same -- same line of      2 thinking that if you're exposed to      3 something that is injuring your DNA and      4 then you take another substance that      5 injures your DNA, that's bad, to speak      6 technically.</p> <p>7 So smokers or given that      8 gastric cancer has come up in quite a few      9 of the dietary studies very commonly,      10 helicobacter pylori infection is a very      11 common cause of gastric cancer. So      12 people who had that infection and were      13 exposed to large amounts of nitrosamines      14 might well be at increased risk. And the      15 data that would support that, the dietary      16 studies, showing gastric cancer is one of      17 the main cancers associated with      18 increased dietary NDMA would support that      19 supposition as well.</p> <p>20 THE WITNESS: Can I ask how      21 much time we have left so we can      22 determine whether to do a break now      23 or plow through?</p> <p>24 MR. SLATER: How much time      25 are we in, Mr. Videographer, please?</p>	<p>Page 370</p> <p>1 MR. TRISCHLER: Go ahead.      2 Q Let me have you turn to      3 page -- I'm really trying to get through      4 and finish up the best I can. So page --      5 no regulatory agency that you've come      6 across has classified NDMA or NDEA as a      7 known human carcinogen. You agree with      8 that; right?</p> <p>9 MR. SLATER: Objection. You      10 can answer.</p> <p>11 A It's classified by most as a      12 probable human carcinogen.</p> <p>13 Q We went through all of it;      14 no one classified it as a human      15 carcinogen; true?</p> <p>16 A My understanding is that      17 it's a probable human carcinogen      18 according to the regulatory agencies.</p> <p>19 Q You would agree that no      20 regulatory agency anywhere in the world      21 has classified it as a known carcinogen;      22 true?</p> <p>23 MR. SLATER: Counsel, didn't      24 he just answer that question twice in      25 a row?</p>
<p>1 THE VIDEOGRAPHER: Six hours      2 and 41 minutes.</p> <p>3 MR. SLATER: It's not      4 possible.</p> <p>5 MS. COHEN: Which part's not      6 possible?</p> <p>7 MR. SLATER: He said six      8 hours and 41 minutes. He said we      9 were at 5 hours and 42 minutes      10 before.</p> <p>11 MR. SANJABI: That was an      12 hour when we went back on.</p> <p>13 MR. TRISCHLER: We could      14 stop for a minute.</p> <p>15 MR. SLATER: We don't need      16 to stop for a minute.</p> <p>17 THE WITNESS: No. If it's      18 18 minutes, I'm good.</p> <p>19 MR. SLATER: Let's just keep      20 going. You're still going; right?</p> <p>21 MS. COHEN: Yes.</p> <p>22 MR. SLATER: Let's keep      23 going.</p> <p>24 MS. COHEN: Do you need to      25 go, though?</p>	<p>Page 371</p> <p>1 MS. COHEN: He actually      2 didn't.</p> <p>3 MR. SLATER: You can answer      4 it again, Doctor.</p> <p>5 A To the best of my knowledge,      6 it's classified as a probable human      7 carcinogen.</p> <p>8 Q And, therefore, not a known      9 human carcinogen; true?</p> <p>10 MR. SLATER: Objection.</p> <p>11 A Yes, to the best of my      12 knowledge.</p> <p>13 Q Right.</p> <p>14 Page 23, I want to ask you a      15 question about that in your report.</p> <p>16 The part here on the latency      17 periods where it says, "The latency for      18 cancer causes in whole or in part      19 contaminated Valsartan -- I'm just going      20 to ask you there.</p> <p>21 This part about the bell      22 curve being the likely latency curve,      23 again, you have no cite there; that's      24 because you don't have anything to cite      25 there; right?</p>

<p style="text-align: right;">Page 374</p> <p>1           MR. SLATER: Objection. You 2       can answer.</p> <p>3       A    Well, again, that's an 4       opinion based on my knowledge of cancer 5       biology, cancer pathology. And it's a 6       typical -- it would be typical for 7       latency periods to be at least somewhat 8       bell-shaped.</p> <p>9       Q    Based on your experience?</p> <p>10      A    Yes, and my knowledge of the 11       medical literature.</p> <p>12      Q    But, again, you didn't cite 13       to anything, nor can you cite to anything 14       right now; true?</p> <p>15      MR. SLATER: Objection. You 16       can answer.</p> <p>17      A    I didn't cite to anything 18       clearly here. But I mean, that's just 19       the way cancers work. It's not like 20       smokers get lung cancer precisely 20 21       years and 17 days after the first 22       cigarette. There's some spectrum to it. 23       Some get early cancer; some get late 24       cancers. This is the way cancer 25       physiology, pathobiology tends to work.</p>	<p style="text-align: right;">Page 376</p> <p>1       countermand IARC's statement there.</p> <p>2       Q    What about in human beings?</p> <p>3       Are there particular types of cancers 4       that you think are most likely when again 5       caused by NDMA and NDEA in your opinion, 6       even understanding that we're obviously 7       in disagreement with?</p> <p>8       A    Yeah, certainly.</p> <p>9           I think you have to start 10       with the dietary studies, what cancers 11       were we seeing in the dietary studies. 12       And from the dietary studies, it seems 13       the GI tract, specifically the stomach, 14       the colon and in particular, the rectum, 15       seem to be target-oriented.</p> <p>16           I would also say that liver 17       would be a high-risk organ based, A, on 18       the animal studies; B on Gomm. And then 19       the dietary studies also point to potency 20       with respect to lung cancer. So those 21       are the ones that preliminary data or in 22       some cases fairly well-established data 23       are pointing to as the most likely 24       cancers. That's not to say that those 25       are the only cancers that could be caused</p>
<p style="text-align: right;">Page 375</p> <p>1       Q    Are there particular types 2       of cancers that you believe that NDMA and 3       NDEA more likely caused in animals?</p> <p>4       A    In animals?</p> <p>5       Q    Yes.</p> <p>6       A    Yeah. Give me a moment.</p> <p>7       Q    Okay.</p> <p>8       A    So in the IARC monograph on 9       nitrosamines and NDMA, it says 10       specifically -- and I reference this 11       paragraph -- "N-nitrosodimethylamine is 12       carcinogenic, and all animal species 13       tested."</p> <p>14           It lists a bunch of animals, 15       including one I never heard of, called a 16       Mastomy.</p> <p>17           "It induces benign and 18       malignant tumors following administration 19       via various routes, including digestion 20       and inhalation in various organs and 21       various species. It produces tumors of 22       the liver, kidney and respiratory tract."</p> <p>23           So as far as the animal 24       studies go, I have no specific feeling or 25       knowledge -- I should say knowledge to</p>	<p style="text-align: right;">Page 377</p> <p>1       by NDMA ingestion. But you asked most 2       likely. And I'm giving you the data on 3       what is most likely.</p> <p>4       Q    Are most human beings 5       exposed to the medical sources of 6       ionizing and radiation?</p> <p>7           MR. SLATER: Objection. You 8       can answer.</p> <p>9       A    I don't know.</p> <p>10      Q    Are most human beings 11       exposed to asbestos in the environment?</p> <p>12      A    Definitely.</p> <p>13      Q    When individuals are exposed 14       to more than one kind of mutagen in their 15       lifetime, can you determine as between 16       them, which one causes cancer?</p> <p>17           MR. SLATER: Objection. You 18       can answer.</p> <p>19      A    It's a very broad question. 20       In some instances, yes; in some 21       instances, perhaps not.</p> <p>22      Q    Carcinogens from cigarette 23       smoking enter the bloodstream?</p> <p>24           MR. SLATER: Objection. You 25       can answer.</p>

1 A Yes. 2 Q Does cigarette smoking cause 3 cancer in human beings in every tissue? 4 MR. SLATER: Objection. You 5 can answer. 6 A No. It goes back to the 7 concept we talked about before of 8 multi-specificity. It's not every 9 tissue. But it's also not entirely 10 restricted tissues either. 11 Q You said in your report -- 12 A For example, cigarette 13 smoking causes bladder cancer. So nobody 14 is inhaling a cigarette through their 15 urethra, hopefully. So the carcinogens 16 are getting into the bloodstream. 17 Q On page 5, you had a comment 18 about -- I can't find it here -- about -- 19 let's see -- "Mutagenic effects likely 20 greater in organs in which the cells 21 replicate frequently (e.g. 22 gastrointestinal tract)." 23 It's on the bottom. That's 24 the -- on the bottom of 5. 25 A Okay. I'm looking. Yes.	Page 378	1 MS. COHEN: I think I'm 2 going to pass the witness now. I 3 don't know if we want to try to 4 finish or not. But I'm going to cede 5 the witness. I'll reserve additional 6 questions if I need to. But I'm 7 largely finished. 8 MR. TRISCHLER: Let's go off 9 the record, please. 10 THE VIDEOGRAPHER: We are 11 now off the record. The time is 12 6:08 p.m. Eastern Time. 13 (A short recess was taken.) 14 MS. COHEN: I'm marking 27, 15 which is the initial production. 16 It's an index of what you sent; 28 is 17 a second production that you sent. 18 And we typed it up; 29 is a third 19 production that you sent; 30 is the 20 fourth production that you sent; and 21 then 31 is the Jakszyns article; and 22 we have 32 which is the Doctor's 2002 23 WHR article binder. 24 (The above-referred-to 25 document was marked as Exhibit 27 for	Page 380
1 Q Which tissues in the human 2 body have the highest proliferation 3 rates? 4 A Well, as the example I give 5 here, gastrointestinal tract, skin, blood 6 cells, hematolymphoid cells. 7 Q And which ones -- 8 MR. SLATER: I'm sorry. Did 9 you finish? 10 MS. COHEN: I thought he 11 said yes. 12 A I think so. Those are the 13 vast ones. 14 Q Which ones would have the 15 lowest proliferation rates? 16 A Neurons are the lowest. 17 Liver cells are fairly long-lived as well 18 in the absence of an insult. Any organ 19 can be stimulated to proliferate. Any 20 cell can be stimulated to proliferate. 21 And there are many different insults to 22 the organ that can cause that. But in 23 the resting state, sort of the 24 homeostatic state, the things I said are 25 applicable.	Page 379	1 identification, as of this date.) 2 (The above-referred-to 3 document was marked as Exhibit 28 for 4 identification, as of this date.) 5 (The above-referred-to 6 document was marked as Exhibit 29 for 7 identification, as of this date.) 8 (The above-referred-to 9 document was marked as Exhibit 30 for 10 identification, as of this date.) 11 EXAMINATION BY 12 MR. GALLAGHER: 13 THE VIDEOGRAPHER: We are 14 back on the record. The time is 15 6:26 p.m. Eastern Time. 16 Q Good afternoon, Dr. Lagana. 17 My name is Patrick Gallagher. I'm a 18 partner with the law firm of Duane 19 Morris. We represent the ZHP parties. I 20 have just a few very limited questions 21 for you. 22 A Okay. 23 Q Do you have your report in 24 front of you? Can you turn to page 8? 25 A Yes.	Page 381

<p>1 Q And the heading on the top 2 of that page is "ZHP Nitrosamine 3 Contamination Levels," the page you're 4 looking at?</p> <p>5 A Yes.</p> <p>6 Q And on that page, you cite 7 to some measurements of reported NDMA 8 levels in certain batches of Valsartan, 9 identify the lowest, the 3.4 ppm; 10 highest, 188.1 ppm. Do you see that?</p> <p>11 A I see it.</p> <p>12 Q Those measurements are 13 measurements of NDMA in Valsartan API. 14 You understand that?</p> <p>15 A Yes.</p> <p>16 Q And you would agree with me 17 that none of the individuals are patients 18 who were prescribed Valsartan took 19 Valsartan API? They all were ingesting 20 finished dosage form; right?</p> <p>21 A Yes.</p> <p>22 Q And also, either in this 23 section of your report or anywhere else 24 in your report, you didn't consider or 25 take into account the amount of time that</p>	<p style="text-align: right;">Page 382</p> <p>1 information getting at the root cause of 2 the impurity and when it was thought that 3 it likely started until the point where 4 Novartis discovered it.</p> <p>5 So in my thinking, yes, I 6 took into account, you know, how many 7 years such contaminated medicines were on 8 the market. I don't recall if I made a 9 specific reference to that in my report.</p> <p>10 Q So you haven't -- in 11 reaching your opinions in your report, 12 you haven't relied on it?</p> <p>13 MR. SLATER: Objection. You 14 can answer.</p> <p>15 A Well, in my reliance list 16 are regulatory press releases and others 17 that talk about the root cause and the 18 year in which the processing, 19 manufacturing process changed. And as I 20 said, it did shape my thinking. So I 21 provided those reliances. And I thought 22 about those issues.</p> <p>23 Q You thought about them, but 24 in your report, you didn't identify that 25 time frame in reaching your opinions?</p>
<p>1 a finished dosage form incorporating ZHP 2 Valsartan API was being sold and 3 distributed to patients, did you?</p> <p>4 MR. SLATER: Objection.</p> <p>5 A Could you rephrase that?</p> <p>6 Q Sure.</p> <p>7 You identified here, 8 levels -- reported levels of NDMA in 9 Valsartan API that was manufactured by 10 ZHP; is that right?</p> <p>11 A Yes.</p> <p>12 Q And that Valsartan API was 13 incorporated into finished dosage forms?</p> <p>14 A Yes.</p> <p>15 Q Dr. Lagana, in this section 16 of your report or anywhere else in your 17 report, you did not consider the amount 18 of time that any finished dosage -- a 19 finished dosage form incorporating 20 Valsartan API manufactured by ZHP is 21 actually available on the market and 22 being distributed to patients?</p> <p>23 A I don't believe I made 24 reference to that set of data in my 25 report. But I certainly saw some</p>	<p style="text-align: right;">Page 383</p> <p>1 MR. SLATER: Objection. You 2 could look at your report. But I 3 object to the question. I'm not sure 4 it makes sense. And I'm not even 5 sure what you're getting at, counsel. 6 A liability question?</p> <p>7 MR. GALLAGHER: No.</p> <p>8 A Yeah. I don't believe I 9 made specific reference to the number of 10 years by which ZHP was producing 11 contaminated Valsartan.</p> <p>12 MR. GALLAGHER: Thank you.</p> <p>13 I don't have any further questions.</p> <p>14 EXAMINATION BY</p> <p>15 MR. SLATER:</p> <p>16 Q Doctor, can you look at 17 page 8, please, the top?</p> <p>18 A Yes.</p> <p>19 Q You see the first sentence? 20 It says, "ZHP documented NDMA testing 21 results in a chart of 783 batches 22 manufactured with the zinc chloride 23 process between December 28, 2011 and 24 May 23, 2018."</p> <p>25 Do you see that?</p>

<p style="text-align: right;">Page 386</p> <p>1 A I see that. 2 Q And then you gave a summary 3 of the levels between 3.4 parts per 4 million and 188.1 parts per million; 5 correct? 6 A Correct. 7 Q And I'm not going to go 8 through all the other information. 9 Earlier, you were being 10 asked by counsel about your opinions on 11 latency and your reference to a bell 12 curve in your report. Do you recall 13 that? 14 A I do. 15 Q Let's talk about the front 16 end of the bell curve. 17 Would that be the shorter 18 term latency period for people who get 19 cancer sooner after ingestion or exposure 20 to the NDMA or NDEA? 21 A Yes. 22 Q At the front end of the 23 curve, what would you say would be the 24 shortest period of time in your opinion 25 that somebody as a general proposition</p>	<p style="text-align: right;">Page 388</p> <p>1 A I do. 2 Q For the higher consumers who 3 took higher levels as compared to the 4 lower consumers who took lower levels of 5 these contaminants, what would their 6 increased risk be in comparison to the 7 people who took the lower levels? 8 MS. COHEN: Objection. 9 Foundation. 10 Q You can answer. 11 A I would expect the rates to 12 be higher and potentially much higher, 13 much higher risk depending on how much 14 NDMA they inadvertently consumed. 15 Q I'm not going to go through 16 your report. 17 But in your report, you 18 addressed those cancers that were 19 reflected in the literature with regard 20 to both animals and humans. 21 Do you stand by what you put 22 in your report based on your review of 23 the Peer Review literature on the cancers 24 that are shown in the published 25 literature being related to the</p>
<p style="text-align: right;">Page 387</p> <p>1 you would believe could get cancer due to 2 the NDMA or NDEA as ingested in this 3 matter? 4 A I think shorter -- less than 5 a year would be hard to -- I would say 6 probably a year or more. 7 Q On the back end of the 8 curve, in your report, you referred to a 9 period of 30 years or more. 10 What does that mean? 11 A Well, I mean, I think that 12 this substance has damaged people's DNA. 13 I think as time goes on, there's going to 14 be more -- more cancer, more time, in my 15 opinion, is going to lead to 16 significantly more cancers. And it could 17 take 30 years or more for those to be 18 known. 19 Q You were asked by counsel 20 about the increased risk, and you 21 referred to the dietary studies, and it's 22 my term, analogizing or being closely 23 akin to the lower levels seen in the 24 Valsartan pills. Do you recall testimony 25 to that effect?</p>	<p style="text-align: right;">Page 389</p> <p>1 substances? 2 MS. COHEN: Objection. 3 Form. 4 A I stand by everything in the 5 report with respect to that. 6 Q Do you have the Gomm study 7 handy which was Exhibit -- 8 A I got it. 9 Q Please look at Gomm, 10 page 360, 360. 11 A Okay. 12 Q In the right-hand column, 13 just above the heading that says 14 "Regulatory and Public Health 15 Implications," there's a paragraph that 16 says, "However, molecular mechanisms 17 known for NDMA in the pathogenesis of 18 liver cancer in experimental animals 19 support an association with NDMA exposure 20 in humans. It may be that NDMA exposure 21 promotes cancer development in already 22 existing, as yet undiagnosed early stages 23 and thus hastens clinical manifestation." 24 I wanted to read that and 25 ask you, counsel was earlier asking you</p>

1 about your opinion about the interaction 2 of the NDMA or NDEA with somebody who has 3 a predisposition of some sort, and, 4 again, those are my words. And you were 5 asked, was there any published Peer 6 Review literature on that topic? 7 Is this published Peer 8 Review literature addressing that topic 9 at least in part? 10 MS. COHEN: Objection. 11 A It is. 12 Q Counsel asked you earlier 13 about the Sörgel article which is 14 Reference No. 2 to your report. Do you 15 recall that? 16 A I do. 17 Q And you were asked about 18 your analogy in your report to a pack of 19 cigarettes. Do you recall that? 20 A I do. 21 Q And you went through the 22 data and indicated that based on the 23 amounts of NDMA noted, that would be 24 comparable to a pack of cigarettes. You 25 remember you said that?	Page 390	1 Q And if you could look at -- 2 and what I just handed you, which is 3 page 5 out of 8 -- 4 A Okay. 5 MR. SLATER: And I could 6 tell you, this is a 7 translation --correct, Chris? -- of a 8 German article? 9 MR. GEDDIS: Yes. 10 Q If you look at page 5 out of 11 8 -- 12 A Okay. 13 Q -- and if you look at the 14 second paragraph, it says, "Accordingly, 15 the mean intake of nitrosamines from food 16 is estimated at a total of 0.3 ug per 17 day. Smoking 20 cigarettes a day can 18 generally increase the exposure to 19 nitrosamines to 17 to 85 ug per day." 20 Is that of significance with 21 regard to counsel's questions as to where 22 you came up with the smoking a pack of 23 cigarettes today and citing to 24 Abdel-Tawab? 25 MS. COHEN: Objection to	Page 392
1 A I do. 2 Q I want to show you what 3 we're going to mark as -- I guess we'll 4 just mark it as Plaintiffs' Exhibit 1. 5 (The above-referred-to 6 document was marked as Plaintiffs' 7 Exhibit 1 for identification, as of 8 this date.) 9 Q And I'm going to put 10 a Post-it note on it in the interest of 11 moving quickly here on a Friday 12 afternoon. So I'm going to put P1 on it, 13 on a Post-it note. I'm going to hand you 14 one. I'm going to hand one to counsel. 15 It's P1. 16 Is this an article that 17 you're familiar with? 18 A It is. 19 Q When you compare that 20 article to the Sörgel, Abdel-Tawab, et 21 cetera, article, are there similar -- any 22 similar authors? 23 A Yes. Abdel-Tawab I believe 24 is a similar author. Let me just pull 25 out Sörgel.	Page 391	1 form. 2 A Yes. I meant to include 3 this as an additional cite at that point 4 of the report. So 22 micrograms is 5 22,000 nanograms which is within the 6 range of what's said here in 20 7 cigarettes. 8 And if you read the next 9 sentence, it makes the inference in 10 comparison with the 22 micrograms of NDMA 11 alone can be obtained by taking a 12 contaminated tablet from the present 13 examination samples. 14 Q With regard to counsel's 15 questions about the accuracy of your 16 references, are you telling us that you 17 saw this article, you were relying on it, 18 but it was not specifically cited in the 19 report? 20 MS. COHEN: Objection to 21 form. 22 A Yes. It was inadvertently 23 omitted. 24 Q Finally, you were asked 25 about the FDA's statements previously;	Page 393

<p style="text-align: right;">Page 394</p> <p>1 okay? You remember that? You were asked 2 questions about a bunch of FDA 3 statements. 4 A I do. 5 Q And one of them, which we 6 marked as -- you don't have to find it, 7 was marked as Exhibit 17, information 8 about nitrosamine impurities in 9 medications.</p> <p>10 On page 4 out of 8, counsel 11 read to you from the fourth bullet point 12 that says, "Nitrosamine impurities may 13 increase the risk of cancer if people are 14 exposed to them above acceptable levels 15 and over long periods of time. But a 16 person taking a drug that contains 17 nitrosamines at or below the acceptable 18 daily intake limits every day for 70 19 years is not expected to have an 20 increased risk of cancer."</p> <p>21 In this case, based on the 22 information that you've been provided, 23 was the level of nitrosamines, 24 specifically NDMA and NDEA, above or 25 below the limits that were set by the</p>	<p style="text-align: right;">Page 396</p> <p>1 form, foundation, calls for 2 speculation on his part. 3 A I do think that is probably 4 what informed the FDA's thinking. 5 MR. SLATER: Thank you. I 6 have no other questions. 7 FURTHER EXAMINATION BY 8 MS. COHEN: 9 Q The only follow-up I have is 10 on the new article that just suddenly 11 appeared just now, which is Plaintiffs' 12 Exhibit 1, this Abdel-Tawab article. 13 MR. SLATER: Just for one, 14 counsel, I'm informed by Mr. Geddis 15 you actually were provided that 16 article. It wasn't referenced 17 specifically in the report. But it 18 was produced to you. 19 MR. GEDDIS: It was in the 20 first production. 21 MR. SLATER: I just wanted 22 you to know that. 23 MS. COHEN: I appreciate 24 that. 25 Q So basically, this was not</p>
<p style="text-align: right;">Page 395</p> <p>1 FDA? 2 MS. COHEN: Objection to 3 form and foundation. 4 Q You can answer the question. 5 A By and large above and in 6 some instances, wildly above. 7 Q And lastly, counsel asked 8 you a bunch of questions about the fact 9 that people were allowed to keep taking 10 their Valsartan until they spoke to their 11 doctor. 12 Is that because the FDA did 13 a balancing and a risk-benefit and said, 14 well, if people go off their blood 15 pressure medication in the short-term 16 like in the next few days or weeks, they 17 could die of things like strokes and 18 heart attacks, whereas we're talking 19 about a longer-term risk with these 20 pills, so let's not have a bunch of 21 people dropping dead from heart attacks 22 and strokes while they get on to other 23 medications? Was that your understanding 24 of the FDA's thinking?</p> <p>25 MS. COHEN: Objection to</p>	<p style="text-align: right;">Page 397</p> <p>1 cited in your report; is that right? 2 A Correct. 3 Q And this was not referenced 4 on the reference sheet in your report; 5 correct? 6 A Correct. 7 Q The number of articles. 8 So you didn't have this at 9 the time you issued your report on 10 July 6th; correct? 11 A I definitely had this. I 12 read this before I wrote my report. I 13 meant I should have included this as a 14 cite in my report. I overlooked doing 15 that. 16 Q And I think you highlighted 17 for us today, 34 different kind of errors 18 and citation; is that a fair statement? 19 MR. SLATER: Objection. You 20 can answer. 21 A Certainly on the three side 22 of things, yeah. 23 Q How many other cites did you 24 miss? 25 A I don't think any.</p>

100 (Pages 394 - 397)

1     Q     This was just given to us in 2 the last couple of days by Mr. Geddis. 3         Do you have this in your 4 materials? 5     A     I read this a while ago. I 6 don't remember exactly when I gave 7 Mr. Geddis the study, or the paper, I 8 should say. 9     Q     But regardless in terms of 10 the quote in your report about the 11 cigarettes, that citation was not in your 12 report; correct? 13    A     That citation should have 14 been two citations. Both -- the Sörgel 15 was appropriate. But also, I should have 16 included a citation to Abdel-Tawab, who 17 really makes the more direct reference to 18 a pack of cigarettes. 19    Q     Let me just quickly, just so 20 I'm clear on that, if you don't mind, 21 show me in this article where the -- in 22 the Abdel-Tawab where the quote is 23 written. 24    A     Sure. Page 5, the second 25 paragraph.	Page 398	1 any other cites. 2     Q     Well, if I had questioned 3 you about this, would you have realized 4 you overlooked this site? 5         MR. SLATER: Objection. You 6 can answer. 7     A     Probably not because if I 8 had realized it before, I would have 9 corrected it. 10    Q     It was only because I 11 focused on that sentence, not being 12 supported by Reference 2, that you even 13 noticed it; correct? 14         MR. SLATER: Objection. You 15 can answer. 16    A     Well, I was surprised I 17 didn't find exactly what I was looking 18 for in the article. And I knew there was 19 something I had read about a German lab 20 study. And this is something that we did 21 produce and that I had reviewed. And 22 this is definitely what I wanted to cite. 23    Q     In the world of publishing, 24 again, I guess usually the journals have 25 people who are usually checking your
1         "Accordingly, the mean 2 intake of nitrosamines from food is 3 estimated to be 0.3 micrograms per day. 4 Smoking 20 cigarettes, a standard pack a 5 day can generally increase the exposure 6 to nitrosamines is 17 to 85 micrograms 7 per day. In comparison with this, up to 8 22 micrograms of NDMA alone can be 9 obtained by taking a contaminated tablet 10 from the present examination samples." 11         So 22 is in between 17 to 12 85; thus, it is equal to the amount of 13 exposure in a package of cigarettes. 14    Q     So you're saying you read 15 this article, you interpreted it as you 16 interpreted it, and you included this 17 statement in your report and didn't have 18 any cite to it? 19    A     Yes. I overlooked including 20 this cite. 21    Q     And sitting here today, you 22 don't know how many other cites you've 23 overlooked, do you? 24         MR. SLATER: Objection. 25    A     I don't believe I overlooked	Page 399	1 work? 2     A     The Peer Reviewers check, 3 yeah. You can also issue a corrigendum 4 for small little things like that. 5         MS. COHEN: Just quickly, we 6 marked 27, 28, 29, 30, a list of the 7 articles that were produced. 8         Can you show us, Chris? 9         MR. SLATER: He didn't say 10 it was on the list. 11         MR. GEDDIS: They made their 12 own lists. I'll go on Dropbox and 13 pull it, so that we're pulling it 14 from the same. 15         MS. COHEN: Can you just 16 maybe tell us, let us know where we 17 can find it? 18         MR. GEDDIS: I can do it in 19 like two seconds. 20         MS. COHEN: So it was 21 produced. 22         MR. SLATER: That's all I 23 have. Thank you. 24         THE VIDEOGRAPHER: We are 25 now off the record. The time is

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1	6:48 Eastern Time. This concludes	1	INDEX (Cont.)
2	the testimony of Dr. Stephen Lagana.	2	Exhibit 9 Sörgel article 206
3	(Time noted: 6:48 p.m.)	3	Exhibit 10 Europeans 219
4		4	Medicines Agency Assessment Report
5		5	Exhibit 11 Report of Paula 229
6	<u>DR. STEPHEN LAGANA</u>	6	Jakszyn
7		7	Exhibit 12 Article entitled 239
8	Subscribed and sworn to	8	Carcinogenicity of some aromatic amines and related compounds
9	before me on this _____ day	9	IARC Monograph 245
10	of _____, 2021.	10	Document entitled 255
11		11	International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH)
12	<u>NOTARY PUBLIC</u>	12	Exhibit 15 Thresher Article 258
13		13	FDA press release 263
14		14	FDA article 266
15		15	FDA article 269
16		20	Expert report of 278
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3	E X A M I N A T I O N	3	Exhibit 24 Al-Kindi article 303
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14	Exhibit 2 Letter, dated 21	16	production index
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16	Lagana	19	
17	Exhibit 4 Expert report of 32	20	
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<p>1                    C E R T I F I C A T I O N 2 3 4        I, ANTHONY GIARRO, a Shorthand 5 Reporter and a Notary Public, do hereby 6 certify that the foregoing witness, DR. 7 STEPHEN LAGANA, was duly sworn on the date 8 indicated, and that the foregoing, to the 9 best of my ability, is a true and accurate 10 transcription of my stenographic notes. 11      I further certify that I am not 12 employed by nor related to any party to 13 this action 14 15 16 17                     18                    ANTHONY GIARRO 19 20 21 22 23 24 25</p>	Page 406
<p>1                    ERRATA SHEET 2                    VERITEXT/NEW YORK REPORTING, LLC 3                    1-800-727-6396 4                    330 Old Country Road    1250 Broadway 5                    Mineola, NY 11501    New York, New York 6                    10001 7                    NAME OF CASE: In Re: Valsartan, Losartan 8                    and Irbesartan Products Liability 9                    Litigation 10                  DATE OF DEPOSITION: August 13, 2021 11                  NAME OF DEPONENT: Dr. Stephen Lagana 12                  PAGE LINE (S) CHANGE    REASON 13                  _____ 14                  _____ 15                  _____ 16                  _____ 17                  _____ 18                  _____ 19                  _____ 20                  _____ 21                  DR. STEPHEN LAGANA 22                  SUBSCRIBED AND SWORN TO BEFORE ME 23                  THIS ____ DAY OF _____, 20___. 24 25                  (NOTARY PUBLIC)    MY COMMISSION EXPIRES:</p>	Page 407

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Federal Rules of Civil Procedure

Rule 30

(e) Review By the Witness; Changes.

(1) Review; Statement of Changes. On request by the deponent or a party before the deposition is completed, the deponent must be allowed 30 days after being notified by the officer that the transcript or recording is available in which:

(A) to review the transcript or recording; and

(B) if there are changes in form or substance, to sign a statement listing the changes and the reasons for making them.

(2) Changes Indicated in the Officer's Certificate. The officer must note in the certificate prescribed by Rule 30(f)(1) whether a review was requested and, if so, must attach any changes the deponent makes during the 30-day period.

DISCLAIMER: THE FOREGOING FEDERAL PROCEDURE RULES ARE PROVIDED FOR INFORMATIONAL PURPOSES ONLY.

THE ABOVE RULES ARE CURRENT AS OF APRIL 1, 2019. PLEASE REFER TO THE APPLICABLE FEDERAL RULES OF CIVIL PROCEDURE FOR UP-TO-DATE INFORMATION.

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COMPANY CERTIFICATE AND DISCLOSURE STATEMENT

Veritext Legal Solutions represents that the foregoing transcript is a true, correct and complete transcript of the colloquies, questions and answers as submitted by the court reporter. Veritext Legal Solutions further represents that the attached exhibits, if any, are true, correct and complete documents as submitted by the court reporter and/or attorneys in relation to this deposition and that the documents were processed in accordance with our litigation support and production standards.

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